

[54] **COMPACT, IMPLANTABLE APPARATUS FOR PUMPING BLOOD TO SUSTAIN BLOOD CIRCULATION IN A LIVING BODY**

[76] Inventor: **Max Shapiro**, 1728 Monticello Dr., Beverly Hills, Calif.

[22] Filed: **Nov. 20, 1969**

[21] Appl. No.: **878,341**

[52] U.S. Cl. 3/1, 3/DIG. 2, 128/1 D, 417/384, 417/385

[51] Int. Cl. **A61f 1/24**

[58] Field of Search 3/1, DIG. 2; 128/1, 214, 128/DIG. 3, 273; 417/383-390

[56] **References Cited**

UNITED STATES PATENTS

2,812,716	11/1957	Gray	128/DIG. 3
2,917,751	12/1959	Fry et al.	3/1
3,148,624	9/1964	Baldwin	3/DIG. 2
3,152,340	10/1964	Fry et al.	3/1
3,359,910	12/1967	Latham	417/478 X

OTHER PUBLICATIONS

"Problems of Artificial Hearts And Their Experimen-

tal Study," by B. Y. Petrovsky et al. Journal of Thoracic and Cardiovascular Surgery, Vol. 57, No. 3, March, 1969, pages 431-441.

Primary Examiner—Richard A. Gaudet

Assistant Examiner—Ronald L. Frinks

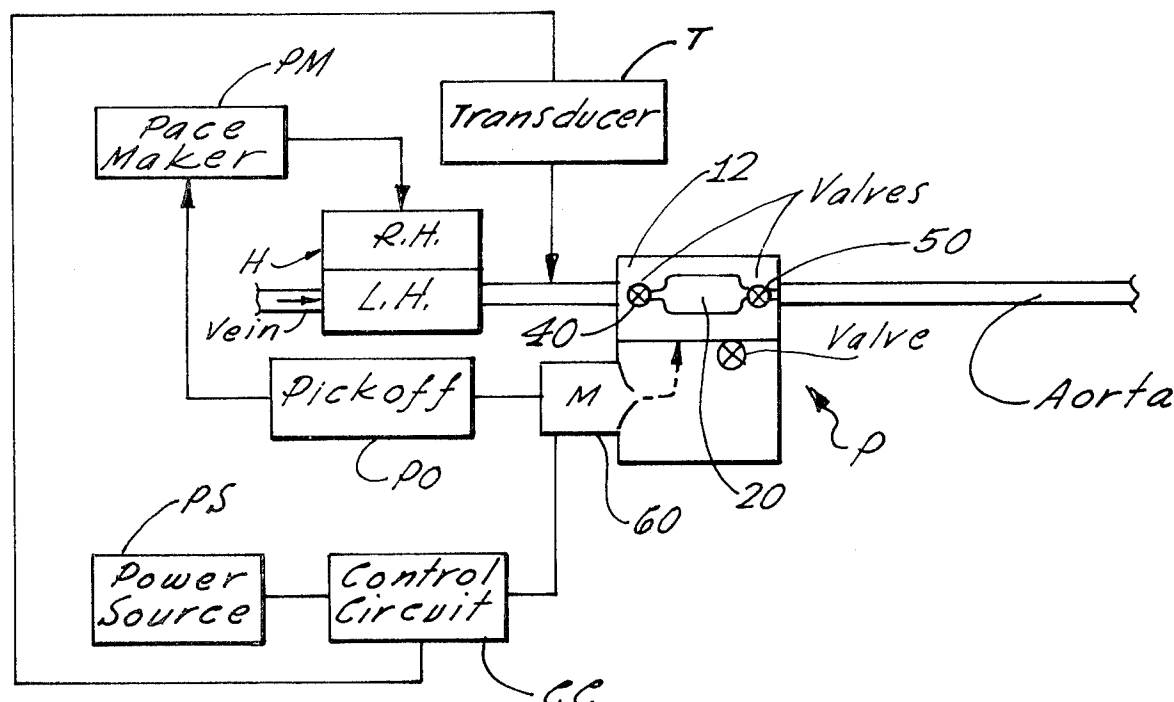
Attorney, Agent, or Firm—Ralf H. Siegemund

[57]

ABSTRACT

An artificial heart system for implant is disclosed in which a deflatable bladder provides a straight-through blood path. The bladder is disposed in a gas filled chamber, the volume of which is controlled by a piston in the immediate vicinity of the bladder to provide pumping action. The piston is driven by a motor. A pressure equalizing bypass as between chamber and atmospheric pressure, and a check valve provide local autoregulation for the pump. A pacemaker can be operated in synchronism with the drive to simulate, for example, the natural right heart while the natural left heart is deactivated or bypassed.

9 Claims, 5 Drawing Figures



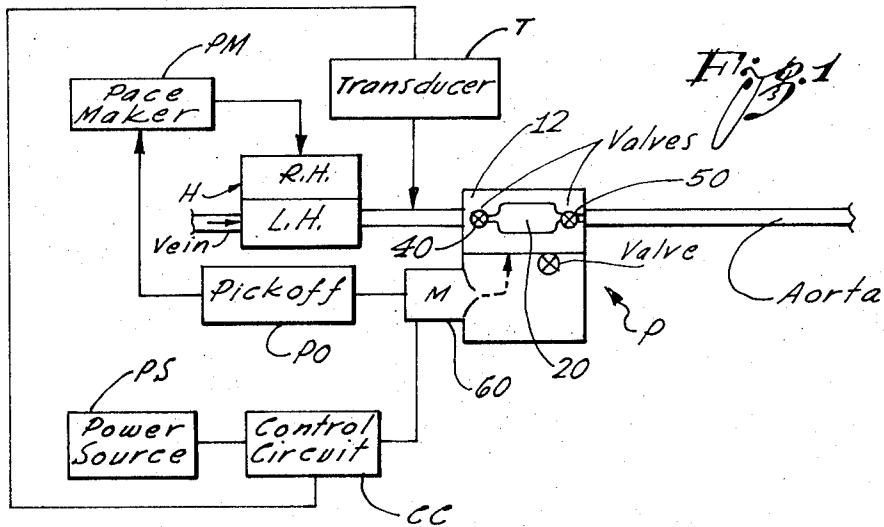


Fig. 4

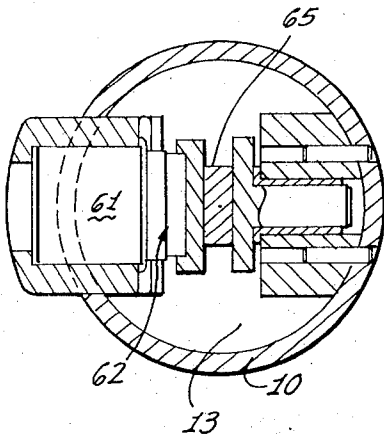
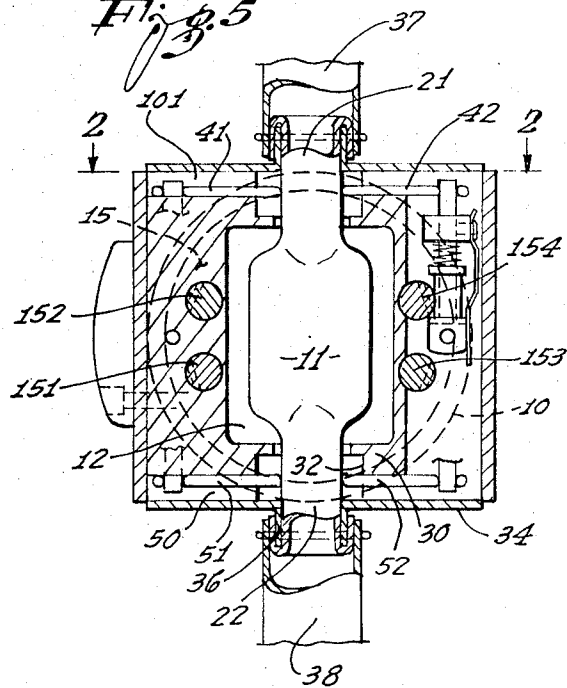


Fig. 5



INVENTOR:
Max Shapiro

By *Smith, Keston & Parrott*
ATTORNEYS

COMPACT, IMPLANTABLE APPARATUS FOR PUMPING BLOOD TO SUSTAIN BLOOD CIRCULATION IN A LIVING BODY

The present invention relates to a pumping apparatus for pumping blood through a living body so as to sustain blood circulation, and more particularly, to improvements in the art of so-called artificial hearts and heart bypass or relief pumps of compact design, preferably for implantation.

The (natural) heart is a muscular organ establishing two pumps which run in synchronism. The main pumping action of each pump is provided by a chamber called the ventricle, whereby the so-called right ventricle pumps blood into the pulmonary artery for passage into the lungs to sustain the pulmonary circulation. The left ventricle pumps blood into the aorta for profusions throughout the body in order to sustain the so-called systemic circulation. The venous return from the systemic circulation leads into an antechamber for the right ventricle, called the right atrium, while the venous return from the lungs lead to an antechamber for left ventricle, called the left atrium. Blood flows from the atria into the ventricles during the so-called diastolic cycle; the blood is compressed in the ventricle, and discharged into the respective arteries during the systolic cycle.

In order to sustain the systemic circulation, the left ventricle has to raise the blood pressure from approximately atmospheric pressure of the venous return from the pulmonary system by about 120 to 150 mm/mercury, or thereabouts. The principal function of a cardiac prosthesis, permanent as well as temporary, is to provide such pumping action at a characteristic which is at least approximately a faithful simulation of normal heart action and can be maintained, in principle, for an unlimited period of time. Simulating the pumping action can thus be regarded as synthesizing the natural alternating diastolic and systolic cycles. The invention relates to a pumping system which provides distinct diastolic and systolic cycles as created by the natural heart.

The pumping operation of a natural heart has been described by so-called Starling's law, according to which the heart pumps all the blood that comes to it without allowing excessive damming of the blood in the veins, of course, within physiological limits. In other words, the heart adjusts its action to the demand. The invention relates to a pumping system which obeys Starling's law.

Aside from mechanical duplication of the pump and duplication of control actions, a cardiac prosthesis must handle blood flow in an atraumatic manner without damaging it. The blood must not stagnate nor incur turbulence, nor must clots be formed and hemolysis has to be avoided. In accordance with the present invention, the following combination is suggested.

A first chamber is provided, serving as pressure chamber and containing an inert gas; air was found to be suitable but nitrogen or some other gas with large molecules (low diffusion rate) may be better. The interior of the chamber is to a considerable extent, occupied by an inflatable and deflatable bladder made of durable, flexible and expandable, rubbery material, or the like. The gas in the chamber does not fill the bladder. The bladder is of elongated construction and has aligned inlet and outlet tubes integral therewith. These tubes are affixed to a pair of aligned openings in the

first chamber and close the openings as far as the interior of the chamber external to the bladder is concerned. Inlet and outlet tubes are respectively connected in the blood path, for example, leading from a vein to an artery. Thus, blood can flow into, through and out of the bladder in an essentially straight through flow path.

The bladder is surrounded by the gas and pressure as well as volume off the bladder is determined by gas pressure acting essentially in direction perpendicular to the bladder surface. Blood flows through the bladder in what can be regarded an axial direction of tube and opening alignment as defined. The bladder inflates and deflates, therefore, essentially radially.

One of the walls closing the chamber parallel to that axial direction is movable toward and away from the bladder and serves as a piston. Adjacent walls of the chamber are extended so that the first chamber is, in part, a piston chamber, but there is a second chamber on the other side of the piston. The second chamber is filled with the same gas as the first chamber and may be maintained at a pressure not dropping below atmospheric pressure.

The second chamber includes short piston linkage translating rotary motion into a reciprocating motion. The rotary motion is provided by a motor disposed adjacent the second chamber and transmitted preferably by a so-called harmonic drive-type converting relatively fast rotation of the motor into slow motion corresponding to a rate for reciprocation in the order of 100cpm. The reciprocating motion imparted upon the piston establishes alternating systole and diastole respectively as compression/arteric discharge and controlled intake cycles.

Assuming the bladder has been filled, a valve in the path of the inlet tube closes, and the piston is moved forward to compress the gas in the first chamber, thereby causing the blood therein to be pressurized. As the gas used is compressible, the blood compression is a gentle one. Shortly thereafter a valve in the outlet tube and leading, for example, to the aorta, opens, and the blood begins to discharge from the bladder into that artery. The valve is opened when pressure is high enough so that systolic pressure can be built up in the artery. The valve remains open for the length of time necessary to generate a proper pulse wave having duration, for example, of 1/4 pulse cycle as in the human heart.

As the piston continues to move toward further compression of the gas in the first chamber, blood is pushed out of the bladder at the arterial systolic pressure until discharged. The first chamber is dimensioned so that for an almost fully protracted piston, gas pressure is above arterial pressure to prevent back-flow of blood.

Shortly before the piston begins to retract, the valve governing the outlet tube in the artery closes. In timed relation thereafter, the inlet valve reopens, particularly when the piston has retracted to such a degree that the gas pressure in the first chamber has dropped to the venous pressure which is about atmospheric pressure. In essence, the retraction of the piston is controlled in such a manner that the volume increase in the first chamber equals the expansion of the bladder as blood flows in under venous pressure. It is essential that the piston generates a slight pressure drop in the expanding first chamber relative to the atrial pressure, but the pressure drop must not be strong enough to produce

collapse of the veins; this is most critical for successful operation of the device.

The venous return versus atrial pressure of a natural heart, has a negatively sloping characteristic with zero return at about 7 mm Hg positive. Flow increases with decreasing pressure but leveling-off begins at a few mm Hg negative. A further negative increase of atrial pressure does not increase and may decrease the venous return. The piston retraction must thus produce and maintain a pressure in the first chamber below a positive pressure amounting to an actual damming of the blood, but above a negative pressure corresponding to the leveling off point of the atrial pressure-venous return characteristics in order to prevent venous collapse. Atmospheric pressure equivalent to zero pressure on the commonly used scale is a very suitable value, so that the first chamber can be brought into communication with the second chamber by a check valve, for example, in the piston, as soon as pressure in the first chamber drops to atmospheric pressure.

The piston thus merely increases the volume of the first chamber so that the bladder can expand as blood from the vein enters without having to work, and without actually being sucked in, i.e., the piston's movement provides the expansion of the bladder so that the venous return blood just flows into the expanding bladder at minimum resistance without being actually sucked in by a vacuum system.

The inlet valve closes at about the time of maximum piston retraction, and just after that time the pressure between the two sides of the piston equalizes, independently from operation of the check valve. Check valve and pressure equalization at the end of a cycle is instrumental in causing the system to obey Starling's law. Moreover, the pressure equalization between the chambers at one point during each cycle is essential for long term operation as the gas must not accumulate on one side or the other of the piston, particularly the compression of the first chamber should always begin from about atmospheric pressure at closed valves.

As the system is designed for a particular maximum capacity of the stroke, which should be above the mean value, the venous return flow may come to a stop prior to complete retraction. However, the pressure-sensitive valve maintains equality of pressure on both sides of the piston so that the first chamber cannot develop negative pressure after blood in-flow has ceased but prior to complete piston retraction.

The inventive system, if used as suggested, operates by bypass or as substitute for ventricle. Heart damage often involves the left ventricle only as the main pumping organ, while the right ventricle serving the pulmonary system is less likely in need of replacement. A pump as described can serve as substitute or replacement of the left ventricle which has been deactivated. It is thus suggested to include a pacemaker into the system and to drive the pacemaker in synchronism with the pump, so that the remaining right ventricle of the natural heart is forced to pump in synchronism with the mechanical pump as described and which has taken over the function of the left ventricle. Alternatively, a second bladder can be inserted, so that a substitute is present for both, left and right heart, operating in harmony with each other; this will be subject of a separate application for patent.

The valves involved in the control of bladder intake and outflow are preferably operated in response to pis-

ton operation, but may be operated by other mechanical or electromechanical means. The valves are actively controlled which permits control of the slope of the pressure pulse at the outlet since there is quite a definite relationship between piston position and gas pressure in the first chamber. Thus, the blood flow does not have to be controlled by pressure responsive valves which are included in the blood path, and the installation of flow impediments in the blood path can be avoided, preventing turbulence clotting and other blood damage.

The valve at the outlet tube of the bladder is opened when the piston has a position corresponding to a particular relative volume reduction in the first chamber which corresponds to a particular pressure increase therein, somewhat in excess of the aortic pressure. This holds true because a particular volume of the gas is compressed always by a particular relative volume reduction, and since the device is always at a constant body temperature, there is a definite relation between piston position and pressure in the first chamber (Boyle's law). The valve governing the outlet tube can thus be opened in dependence upon position of the piston indeed.

One can readily see that employment of a compressible fluid is essential for a smooth and sufficiently elastic operation. The aortic valve of the output side of the bladder is closed just prior to maximum protraction of the returning piston. Again, piston position response can be used as controlling factor, as the blood will not flow back into the bladder as long as the piston moves toward further compression. The inlet valve opens during retraction of the piston when the pressure in the pressure chamber has almost reached atmospheric pressure. Again, this can be made dependent upon the position of the piston as there is a definite relationship between pressure and volume, particularly for completely empty bladder. The inlet valve should remain open until the piston is completely retracted.

It should be noted that an asymmetry could be included in the piston operation in that its protracting phase is shorter than its retracting phase, which feature makes the pump particularly comparable with the rather long diastole and relatively short systole as is the case of the natural heart.

The system can be designed to operate normally at less than full capacity so that the pump provides the equivalent of the heterometric autoregulation which is one of the intrinsic mechanisms for adapting the natural heart to a variable venous return. As the driving motor can be provided to operate at a constant speed characteristic for a chosen range of torque, the pump has also the equivalent of homeometric autoregulation. Measuring the venous return pressure and controlling the motor in pumping speed can be used to provide the equivalent of the intrinsic autoregulation. All these various features together cause the artificial device to obey Starling's law.

While the specification concludes with claims particularly pointing out and distinctly claiming the subject matter which is regarded as the invention, it is believed that the invention, the objects and features of the invention and further objects, features, and advantages thereof will be better understood from the following description taken in connection with the accompanying drawings in which:

FIG. 1 illustrates schematically a system for operation as a left heart substitute;

FIGS. 2 and 3 are longitudinal section views through a heart prosthesis incorporating the principles of the invention in accordance with the preferred embodiment thereof; and

FIGS. 4 and 5 are longitudinal section views of the structure shown in FIGS. 2 and 3 and as indicated therein.

Proceeding now to the detailed description of the drawings, in FIG. 1 thereof there is illustrated a system in accordance with the preferred embodiment for practicing the invention and which includes a prototype that has been successfully employed in animal experiments. The system includes a pump P with a housing 10, having a gas filled pressure chamber 12, the volume of which and the pressure therein being under control of a piston 15 reciprocating by operation of linkage, which in return is driven by a motive unit 60.

A bladder 20 in chamber 12 is provided as artificial ventricle. In the conducted experiment, the bladder was interposed in the arterial circulation, between the left atrium and the descending aorta. The left ventricle was deactivated with a balloon catheter, closing the AV valve as well as the aortic valve, thus providing straight-through flow from the left atrium through the bladder 20 to the descending aorta.

Thus far the description relates to a system as it has been actually used to sustain blood circulation in a dog. It was found, that the heart as a whole was not deactivated to the extent that the pulmonary circulation could not be sustained, instead the right heart continued to function. As a backup, the following auxiliary equipment was planned. A pick-off unit PO responds to the phase of the pump P to drive a so-called pacemaker PM stimulating the natural right heart RH in synchronism with the operation of pump P. The pacemaker is normally an autonomous electronic oscillator, however, such oscillator can always be forced into synchronism with a master frequency which, in this system, is derived from the motive unit 60 by pick-off PO. The pacemaker PM provides electrical stimulating pulses in synchronism with its oscillations. The system can be supplemented, for control, by a pressure transducer T on the input side of bladder 20 to monitor what is, in effect, the venous return pressure to govern a control circuit CC interposed between a power supply PS and the motive unit 60. In the experiment conducted, motive unit 60 was directly coupled to the power supply unit PS comprised of batteries.

Turning now to the description of FIG. 2, et seq., the pump includes the housing 10 which basically defines two chambers along an axis 11. One of the two chambers has been referred to repeatedly in the specification as the first or pressure chamber and is denoted by reference numeral 12. The second chamber 13 is separated from chamber 12 by the movable piston 15, the piston being particularly movable along axis 11 in reciprocating motion, thereby alternately decreasing and increasing the volume of pressure chamber 12, while concurrently increasing and decreasing the volume of chamber 13. The forward or compression stroke or cycle refers to a decrease in volume of chamber 12 by protraction of piston 15 and a concurrent increase in volume of chamber 13. Correspondingly, a decompression or suction stroke or cycle refers to enlargement of chamber 12 during retraction of piston 15.

The decrease or the increase in volume in chamber 13 does not necessarily infer corresponding pressure change in chamber 13, since chamber 13 may communicate with the exterior to maintain at least approximately atmospheric pressure. On the other hand, the pressure in chamber 12 varies definitely with reciprocation of piston 15.

Housing 10 is provided either for an implant in total, or in part, and it is essential that it is of compact design to support all elements needed to provide, in effect, an alternating sequence of systoles and diastoles. Chamber 12 is occupied to a considerable extent by bladder 20. Bladder 20 is provided with an inlet tube 21 and an outlet tube 22. The two tubes 21 and 22 are aligned in undeformed configuration of the bladder, which is positioned in chamber 12 at an orientation so that the aligned tubes 21 and 22 extend transverse to axis 11.

Wall portions of housing 10 defining the particular chamber 12 have two essentially, registering openings 31 and 32. The inlet and outlet tubes 21 and 22, respectively, traverse these openings and are centrally positioned therein. Accordingly, the two openings 31 and 32 are coaxial and transverse to axis 11. The openings 31 and 32 are covered to some extent by coverplates 33 and 34 having short tubes 35 and 36, respectively. The tubes 21 and 22 are respectively received by tubes 35 and 36. The ends of tubes 21 and 22 are turned back and surgical connection tubes 37 and 38 are tightened thereto. Tube 37 is surgically affixed to a blood vessel to receive the blood flowing toward the heart in one of the venous return paths. Tube 38 is connected to the aorta.

As can be seen from the drawings, bladder 20, with inlet and outlet tubes provides a straight-through flow path of blood when flowing from the venous return to the aorta, bypassing the left heart or flowing through without being pumped.

The bladder 20 is surrounded by the gas which fills that portion of chamber 12 not occupied by the bladder. This gas can be regular air. However, nitrogen, as an inert gas or a gas with large molecules to prevent loss through the bladder is preferred. Seals 23 and 24 respectively seal the apertures 31 and 32 where the tubes 21 and 22 pass through to seal the interior of chamber 12. As the gas pressure is increased, the bladder is radially contracted with reference to the axis of the flow path of blood through the bladder. Relaxation of pressure in chamber 12 may result in bladder expansion.

The pressure in chamber 12 is controlled by piston 15, moving up to the immediate vicinity of the bladder during compression of gas in chamber 12. It is an important aspect of the construction that axis 11, along which the piston moves to and from the bladder, is transversely disposed in relation to and intersects the axis of blood flow. The reason for this lies in the following. For reasons of space, chamber 12 should be kept as small as possible and the piston should have relatively large surface so that the stroke length of the piston can be small. The volume of the bladder is an operating parameter and the change in volume of chamber 12 during each stroke is always equal to the volume of the fully expanded bladder. A symmetric disposition of the axes with respect to each other optimizes the construction for the given parameters.

The total amount of gas compressed is not very large, and the compressibility thereof is a material factor for

smooth operation. Moreover, in spite of short piston stroke length, the pressure in chamber 12, as developed by a compressible medium in the vicinity of bladder, can still be very accurately controlled by operation of the position of piston 15.

Inflow and outflow of blood in relation to bladder 20 is controlled by operation of a pair of valves 40 and 50. The inlet valve 40 is comprised of a pair of shutter blades 41 and 42 running in a recess 101 on one side of housing 10, symmetrically disposed to opening 31. The two shutters 41 and 42 move in unison toward or away from each other along an axis which is transverse to both axis 11 and the axis of blood flow. The shutter blades may have a fairly wide section at the end nearest the inlet tube.

The shutter or valve blades 41 and 42, when moving toward each other, squeeze inlet tube 21 and constrict the passageway therethrough. The valve is regarded as closed when the shutters have squeezed opposite wall portions of tube 21 against each other so that the cross section of the flow path through the tube is, in effect, reduced to zero. When the shutters move away from each other, tube 21 dilates and blood flows through the tube uninhibited. As to outlet tube 22, there is a pair of shutter blades 51, 52 for valve 50 running in a recess 102 and operating similar to valve 40. However, the timing of operation of the two valves differs.

The details of an advantageous actuating mechanism for the valve shutters is part of a separate patent application. Briefly, the piston 15 is provided with actuator rods 151, 152, 153 and 154 extending into the interior of chamber 12. The rods 151 to 154 are provided with cams for reasons of timing the valve opening and closing and act on spring-biased linkage levers which in turn operate the valve shutters 41, 42, 51 and 52; shutters 41 and 42 are operated in unison and in dependence upon the position of the piston. Shutters 51 and 52 are also operated in unison but essentially anticlockwise to the timing of operation of shutters 41 and 42.

The valves operate as controllable constrictions of smooth contour, particularly during periods of respective valve opening or closing operation as the respective shutter blades approach or recede. The valve operates without generation of turbulence, nor do they create regions of stagnation, since valve shutter blades are not positioned directly in the flow path of the blood. The closed position of the valve is positively maintained through the shutters external to the flow path proper.

Rods 152 and 154 act in unison and respectively operate linkage to cause the shutter blades 41 and 42 to open the passage through inlet tube 21 during most of the suction phase of piston 15, closing the passage shortly before the beginning of the compression phase and keeping the passage closed throughout compression. Rods 151 and 152 cause blades 51 and 52 to open outlet tube 22 during compression phase but only after piston 15 has decreased the volume of chamber 12 to such an extent that the pressure has risen somewhat above the systolic pressure in the aorta. Tube 22 is then opened and remains open throughout the remainder of the compression phase. Valves 40 and 50 are never open concurrently, but there are brief phases when they are both closed, particularly after completion of discharge of the bladder.

Chamber 13, on the other side of piston 15, is provided with a separate housing which is still part of hous-

ing 10 and contains the motor unit 60. The motive unit 60 includes a d-c motor 61 having its rotary output coupled to a harmonic drive 62. The drive 62 is actually a transmission which converts the relative fast rotating motion of motor 61 to a slow rotary motion about the same axis. The outstanding characteristics of the harmonic drive is that essentially by operation of two, three or more rotating gear elements, a speed reduction of 100:1 and more is obtainable. In conventional gears, meshing gear wheels engage in that tooth-flanks slide on each other. The gears involved in a harmonic drive do not revolve on each other in frictional contact as between engaging teeth; instead, the teeth of the driving member of a harmonic drive move to and from teeth of the driven member thereof in directions normal to the respective surface about to engage and after engagement with little or no relative motion during engagement. There is very little frictional contact between the several teeth as teeth flanks move hardly at all tangentially relative to each other when in contact. The harmonic drive is a very compact and very low-wear transmission, and was found highly suitable for the present purpose.

The output side of harmonic drive 62 provided with an eccentrically located pin 63 linked to an element which can be described as a piston rod 65. A pivot pin 66 links piston 15 to piston rod 65. A balancing shaft 67 is journaled in a bearing block 68 and carries a disk 69 receiving pin 63 to relieve the drive system from cantilever action. Shaft 67 is coaxial to the output axis of harmonic drive 62.

The revolving motion of pin 63 about the common axis of drive 62 and of shaft 67 is translated into a reciprocating motion of piston rod 65 and piston 15. The stroke length is determined by the two possible extreme positions of pin 63 along axis 11. FIGS. 2 and 3 show the fully retracted position of the piston at the end of the diastole and the beginning of the systole.

The simple linkage provided by the pin-rod arrangement 63-65 establishes similar suction and compression cycles as the piston position vs time follows a sinusoidal characteristic. As an example of one method to extend the diastole and to shorten the systole, a slotted mask can be interposed forcing pin 63 to run in a slot. Pin 63 can be made radially movable where journaled to the rotary output member of the harmonic drive. A cam slot for guiding pin 63 can be contoured so that the timing between extreme piston positions differ, suction to last longer than compression. The cam slot additionally can be contoured so as to simulate closely the natural inflow rate of blood from the venous return path. This way piston motion alone establishes pressure in chamber 12 throughout the suction cycle, for an even flow of blood into the bladder.

As particularly illustrated in FIG. 3, housing 10 is provided with an indentation 14 serving as a bypass, controlled leakage path, or communication duct between chambers 12 and 13 to become effective when the piston is in or very near the completely retracted position. Atmospheric pressure can be established and maintained in chamber 13, for example, through a duct leading to the exterior of the body in which the unit is implanted; this was the case in the unit actually tested. Alternatively, the unit can be sealed after an internal pressure at or near atmospheric pressure has been established in both chambers. In this case a gas other than air can be used. Pressure balance at or near atmo-

spheric pressure is positively established in both chambers upon maximum retraction of the piston, toward the end of each simulated diastole through duct 14.

A check valve 70 in piston plate 15 ensures, on the other hand, that the pressure in chamber 12 is never allowed to fall below atmospheric or near atmospheric pressure maintained or existing in chamber 13. Check valve 70 and bypass 14 are instrumental in the autoregulation of the pump to meet variable demands resulting from variations in the venous return. If chamber 13 is sealed, it may have an expandible wall so that pressure therein remains essentially constant during piston motion. The wall will expand into the body cavity. In the alternative one can provide an auxiliary bubble communicating with chamber 12, serving as variable reservoir and expanding into the body cavity.

It can readily be seen that in particular, during the diastole, when piston 15 retracts, the volume of chamber 12 not occupied by bladder 20 remains essentially the same with the pressure being near atmospheric level. The bladder is thus forced to expand. As the tube 21 dilates shortly after piston retraction has begun, blood from the venous return is permitted to enter through tube 21 at the rate of expansion. The blood is thus positively pulled into the bladder, indirectly by the piston, without involving gas flow into or out of chamber 12. The gas serves merely as a resilient linkage as between piston and bladder. Only when the inflow of blood into the expanding bladder tends to drop, valve 70 will open to provide, so to speak slack to the "linkage."

During the systole, the gas serves as a gentle compressure medium for the blood in the bladder. Soon after beginning of a compression cycle, tube 22 dilates by opening of blades 51-52 and blood is pushed out of the bladder into the aorta, the pushing being provided actually by the piston with the expanding gas serving again as elastic linkage. The pressure in chamber 12 drops to the value of the aortic pressure to maintain equilibrium. As piston 15 moves still towards further reduction of the volume of chamber 12, blood is pushed out of the bladder but cannot flow back. Shortly before piston retraction begins, valve 50 closes.

As was briefly alluded to above, it can be shown that the pump synthesizes all of the intrinsic mechanism employed by the natural heart for adapting the pumping power to the demand as represented by the amount of the venous return. The volume of bladder 20 can be selected to have dimensions that, for the normal rate of venous return, the bladder is not completely inflated by one stroke. Moreover, the change in volume of chamber 12 by operation of piston 15 should be somewhat larger than the volume of normal venous return. This way a reserve volume capacity is available in bladder 20, as well as in chamber 12, for cases of a higher than normal return.

Assuming that at an instant the venous return has dropped below the amount returned during a previous stroke, cavity 12 will tend to develop negative pressure as the blood flow into bladder 20 will decline while the retracting piston still expands chamber 12 but at a higher rate than the volume of the inflating bladder increases. Accordingly, valve 70 will open to prevent negative pressure from developing in chamber 12 while the piston still retracts. This, however, increases the amount of gas in chamber 12. During the next compression stroke there is produced the same absolute volume reduction of chamber 12 but acting on a larger

volume of gas while the bladder is filled less. Compression always begins from atmospheric pressure so that the relative pressure increase is less than before, commensurate with a slightly reduced aortic pressure. During the next diastole-retraction of the piston and assuming the venous return remains at the previous reduced level, valve 70 will not respond as the pressure in chamber 12 will reach atmospheric level only at the point of complete retraction, i.e., by the time piston 15 has reached bypass 14. It follows that as long as the venous return does not change, valve 70 will not open but pressure in chamber 12 will tend to drop below atmospheric pressure at about the time piston 15 has reached bypass 14.

Should the venous return suddenly increase, atmospheric pressure in chamber 12 may not have been reached by the time piston 15 has completely retracted as there is too much gas in chamber 12. As piston 15 reaches bypass 14 that excess gas will discharge from chamber 12 by the pressure equalization process. It is thus advisable to adjust the system so that inlet valve 40 (shutters 41, 42) closes only after pressure equalization between chamber 12 and 13 through bypass 14 to fill bladder 20 with at least most of the venous return during this diastole about to be completed. During the next cycle the gas volume in chamber 12 is reduced, permitting bladder 20 to fill more. This may continue during several strokes until a quantity of gas is removed from chamber 12 equivalent to the increase in volume of the venous return.

It follows that the system always regulates itself toward a condition so that the valve 70 is just about to respond to a pressure drop by the time piston 15 reaches bypass 14. Thus, the relative change in volume of expandable bladder and the change in gas in chamber 12 operates as an inherent adaptation of the geometry to variations in the venous return. As one can see, therefore, operation of the pump has an intrinsic mechanism which is the equivalent of the heterometric autoregulation of the natural heart.

In case of employing a sealed system either chamber 12 or chamber 13 must be variable in volume, independently from piston operation. In case chamber 13 is made variable, the situation is directly analogous to a chamber open to the outer atmosphere. The walls of chambers 13, or a portion thereof can be made expandable into the body cavity. As the body has atmospheric pressure internally essentially the same pressure is maintained in chamber 13 by operation of wall flexing and expansion. The autoregulation outlined above will thus function analogously, as atmospheric pressure is maintained in chamber 13 throughout a piston cycle now by external pressure effective through the expandable wall, the decisive difference, of course, being that a closed gas system, without communication to the extension permits utilization of a gas other than air.

In lieu of or in addition to expandable walls for chamber 13, chamber 12 may be provided with variable volume. This can be obtained, for example, by placing the unit P or a portion thereof in a closed but expandable sack communicating with chamber 12. The expansion of that sack varies in unison with expansion of bladder 20. If little blood is sucked in, the sack inflates only slightly, if much blood is sucked in, the sack inflates more. In this case, neither valve 70 nor bypass 14 are required for autoregulation, but bypass 14 is still

needed to prevent unidirectional leakage between the chambers.

In the latter case, chamber 12 being provided with a variable volume extension, the pressure in the sack can be above atmospheric pressure and actually varies in a range between about atmospheric pressure and maximum pressure in chamber 12, above atmospheric pressure for fully protracted piston which, of course, is above "body pressure." In the first case, chamber 13 having expandable wall, the chamber has maximum pressure for fully retracted piston, but this is at atmospheric pressure. As the piston moves forward, pressure in chamber 13 tends to fall except that atmospheric body pressure causes wall contraction to the effect that the volume and pressure of chamber 13 remain about constant. A closed system is subject of a separate patent application.

Turning back to the description of the drawing, motor 61 should have a constant speed vs. torque characteristics within the operating range. It does not change speed if more power is demanded for reasons of an increased demand in pumping power, instead, the motor will consume more power which is analogous to a metabolic change. Thus, the system automatically assumed the function of the homeometric autoregulation as provided by the natural heart.

It follows from the foregoing that the heart prosthesis, relief or bypass device as described, obeys Starling's law. The so-called intrinsic autoregulation of the natural heart can be provided by speed control of motor 61 as was outlined above with reference to FIG. 1 in response to pressure in or near tube 21.

In lieu of pressure controlling the communication between chambers 12 and 13 by operation of valve 70, a pressure transducer in the chamber 12 could be provided in order to provide speed control of motor 61, so as to slow down the piston when the pressure in chamber 12 tends to drop too low a value or to speed up if the demand so requires. Here, then, the heart rate is the predominantly controlled factor for adapting the pumping power to the venous return at all times.

A combination of the two controls is probably the best solution particularly for reasons of choosing as small dimensions as possible. The system normally may operate with a complete filling of the bladder for each stroke. In case the venous return falls or increases, the heart rate is respectively decreased or increased by decreasing or increasing the speed of motor 61. Check valve 70 responds to emergencies only and there is always pressure equalization between chambers 12 and 13 at the end of a stroke when the piston is completely retracted, particularly in order to prevent, as outlined above, accumulation of gas on one side of the pumping system.

The invention is not limited to the embodiments described above, but all changes and modifications thereof not constituting departures from the spirit and scope of the invention are intended to be included.

I claim:

1. In an artificial heart serving as a complete heart substitute, or a bypass, or a relief, the combination comprising:

first means defining a pressure chamber filled with gas, having aligned openings respectively on opposite sides, further including a piston movable transverse to the direction of alignment of the openings,

for increasing volume, and decreasing pressure, and vice versa, in the chamber;

a deformable bladder suspended in the chamber to be surrounded by the gas in the chamber and having aligned inlet and outlet tubes, respectively placed in the openings, thereby, closing the chamber as to these openings, the inlet and outlet tubes provided for respective connection to venous and/or arterial blood vessels;

second means connected to the first means, and serving as piston chamber extension on the side of the piston opposite the side thereof facing the pressure chamber, the second means defining a second chamber filled with the same gas as the first chamber, there being duct defining means to cause communication between first and second chambers in a retracted position of the piston relative to the first chamber;

motor means supported by the second means and providing a rotary output;

third means linking the rotary output of the motor means to the piston for imparting upon the piston a reciprocating motion; and

valve means for opening and closing the flow path in the inlet and outlet tubes anticyclically and in synchronism with the pressure change in the pressure chamber and the bladder as controlled by the piston.

2. In an artificial heart as set forth in claim 1, including means for maintaining substantially constant pressure in the first chamber during piston retraction.

3. In an artificial heart as set forth in claim 1, the piston being a flat disk, there being guide posts on the piston, the first means being a housing with bores receiving the posts to inhibit tilting of the piston.

4. In an artificial heart as set forth in claim 1, there being fourth means to maintain essentially atmospheric pressure in the second chamber.

5. In an artificial heart as set forth in claim 4, the fourth means including a duct leading from the second chamber to the outer atmosphere.

6. In an artificial heart as set forth in claim 1, the means for linking, including a harmonic drive to change the relatively fast rotation of the motor means to a slow rotation commensurate with the cycle of the piston.

7. In an artificial heart as set forth in claim 1, the valve means including symmetrical shutter means operated by the piston for squeezing and dilating the tubes of the bladder.

8. In an artificial heart serving as heart substitute, bypass or relief, the combination comprising:

first means defining an enclosure and including wall portions defining a piston chamber;

a piston in the piston chamber biparting the interior of the first means to define first and second chambers respectively facing opposite sides of the piston;

the enclosure being filled with compressible gas, the enclosure having a pair of openings of the first chamber;

a deformable bladder disposed in the first chamber surrounded by the gas therein and having inlet and outlet tubes respectively passing through the openings of the pair, there being means to seal the openings at the tubes;

relief valve means disposed between the first and the second chamber to prevent the pressure in the first chamber to drop below a particular value;
means in the enclosure defining bypass means inter-
connecting the first and second chambers when the
piston has position corresponding to maximum vol-
ume of the first chamber, the second chamber hav-
ing the particular value of pressure at least during
the last phase of piston retraction to said position;
means coupled to the piston for imparting reciprocating motion upon the piston; and
means for providing alternating constriction and dilation of the tubes, anticyclically to each other, and in synchronism with the piston reciprocation.

9. In an artificial heart serving as a complete heart substitute, or a bypass, or a relief, the combination comprising:

- first means defining a pressure chamber filled with gas, having aligned openings respectively on opposite sides, further including a piston movable transverse to the direction of alignment of the openings, for increasing volume, and decreasing pressure, and vice versa, in the chamber;
- a deformable bladder suspended in the chamber to be surrounded by the gas in the chamber and having aligned inlet and outlet tubes, respectively

placed in the openings, thereby closing the chamber as to these openings, the inlet and outlet tubes provided for respective connection to venous and/or arterial blood vessels;
second means connected to the first means, and serving as piston chamber extension on the side of the piston opposite the side thereof facing the pressure chamber, the second means defining a second chamber filled with the same gas as the first chamber;
motor means supported by the second means and providing a rotary output;
third means linking the rotary output of the motor means to the piston for imparting upon the piston a reciprocating motion;
valve means for opening and closing the flow path in the inlet and outlet tubes anticyclically and in synchronism with the pressure change in the pressure chamber and the bladder as controlled by the piston; and
means for providing flow of gas between the first and the second chamber during piston retraction corresponding to the diastole to maintain the pressure in the first chamber essentially constant.

* * * * *

30

35

40

45

50

55

60

65