TITLE

Fatigue testing system for prosthetic devices

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CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. application no. 14/137,313 filed 20 December 2013 entitled “Fatigue testing system for prosthetic devices,” which is a continuation of U.S. application no. 12/718,316 filed 5 March 2010 entitled “Fatigue testing system for prosthetic devices,” which claims the benefit of priority pursuant to 35 U.S.C. § 119(e) of U.S. provisional application no. 61/158,185 filed 6 March 2009 entitled “Apparatus and method for fatigue testing of prosthetic valves,” which are hereby incorporated herein by reference in their entirety.

TECHNICAL FIELD

[0002] The technology described herein relates to systems and methods for fatigue testing of prosthetic devices, in particular, but not limited to, prosthetic vascular and heart valves, under simulated physiological loading conditions and high-cycle applications.

BACKGROUND

[0003] Prior prosthetic valve testing apparatus and methods typically use a traditional rotary motor coupled with mechanisms to produce regular sinusoidal time varying pressure field conditions. To accurately simulate physiologic conditions and/or produce a more desirable test condition, especially at accelerated testing speeds, a non-sinusoidal time dependent pressure field may be desired. This is not easily accomplished with a mechanistic approach. Furthermore, current systems employ a flexible metallic bellows or conventional piston and cylinder as drive members to provide the pressure actuation. Flexible metallic bellows are not ideal because they require high forces to operate and resonate at frequency, necessitating the use of larger driving systems and limiting the available test speeds. Piston and cylinder arrangements are not ideal because the seals employed in these systems are subjected to fiction and thus have severely limited life in high cycle applications.

[0004] The information included in this Background section of the specification, including any references cited herein and any description or discussion thereof, is included for technical reference purposes only and is not to be regarded subject matter by which the scope of the invention is to be bound.

SUMMARY

[0005] A design for a fatigue testing system for cyclic, long-term testing of various types of prosthetic devices (e.g., cardiac valves, vascular valves, stents, atrail septal defect technologies, vascular linings, and others) is designed to impart a repeating loading condition for the test samples during a test run. However, the system is also designed to be variable in its abilities so it can accurately test multiple technologies. Thus, the system may be variably configured depending upon the device being tested to impart a particular loading profile to repeatedly expose the prosthetic device being tested to desired physiological loading conditions during a testing run. The purpose is to simulate typical or specific physiologic loading conditions on a vascular or heart prosthetic valve, or other prosthetic technology, at accelerated frequency over time to determine the efficacy, resiliency, and wear of the devices.

[0006] Fatigue testing is accomplished by first deploying the prosthetic device in an appropriately sized sample holder, e.g., a rigid or flexible tube, canister, housing or other appropriate structure for holding the device being tested. The sample holder is then placed between two halves of a test chamber that together form a reservoir for a working fluid. The test chamber is in turn mounted to a drive system. The sample holder and valve being tested are then subjected to physiological appropriate conditions which may include: pressure, temperature, flow rate, and cycle times.

[0007] An implementation of a drive system for the fatigue testing system may include a linear actuator or magnetic-based drive motor coupled to a flexible rolling diaphragm. The drive system is coupled to a lower opening in the test chamber and is in fluid communication with the fluid reservoir in the test chamber. The flexible rolling diaphragm (or “rolling bellow”) is reciprocally moveable to pressurize and depressurize fluid and interacts with the lower section of the fluid reservoir to provide a motive force to drive the working fluid through its cycles within the test chamber, including the sample holders.

[0008] Testing and test conditions are controlled by a control computer that permits both input of test conditions and monitors feedback of the test conditions during a testing run. Computer system control may be either an open loop control that requires user intervention in the event a condition falls outside pre-set condition parameters or a closed loop control system in which the computer monitors and actively controls testing parameters to ensure that the test conditions remain within the pre-set condition parameters.

[0009] The fatigue tester is capable of simulating physiologic conditions on prosthetic devices at an accelerated rate. The fatigue tester may also be configured to create either sinusoidal or non-sinusoidal pressure and/or flow waveforms across the prosthetic devices. Pressure waveforms may also be applied that produce a pre-defined pressure gradient over time to a prosthetic device being tested.

[0010] In one exemplary implementation, a device for simultaneous cyclic testing of a plurality of prosthetic devices is composed of a test chamber, a drive motor and a fluid displacement member. The test chamber is pressurizable and has a fluid distribution chamber with a first manifold defining a plurality of ports configured to receive and fluidicly couple with a first end of each of a respective plurality of sample holders. The fluid distribution chamber also defines an aperture in a lower face in fluid communication with a pressure source. The test chamber also has a fluid return chamber with a second manifold disposed opposite and spaced apart from the first manifold of the fluid distribution chamber. The manifold of the return chamber defines a plurality of ports configured to receive and fluidicly couple with a second end of each of the respective plurality of sample holders. A fluid return conduit both structurally and fluidily connects the fluid distribution chamber to the fluid return chamber. The test chamber also has a compliance chamber which provides a volume for holding a gas or an elastic material that compresses under a pressure placed upon fluid in the test chamber and allows fluid in the test chamber to occupy a portion of the volume. The drive motor is configured to operate cyclically, acyclically, or a combination of both. The fluid displacement member is connected with and driven by the drive motor to provide the pressure source that increases and decreases a pressure on fluid in the test chamber. In this manner, cyclic and acyclic fluid pressures may be maintained throughout the test chamber.

[0011] In another exemplary implementation, a device for accelerated cyclic testing of a valved prosthetic device includes a pressurizable test chamber. The pressurizable test chamber contains test system fluid and is further composed of a fluid distribution chamber, a fluid return chamber, a fluid return conduit, and an excess volume area. The fluid distribution chamber is positioned on a first side of the valved prosthetic device and is in fluid communication with a pressure source. The fluid return chamber is positioned on a second side of the valved prosthetic device. The fluid return conduit is both structurally and fluidily connects the fluid distribution chamber to the fluid return chamber. The excess volume area is in fluid communication with the fluid return chamber and provides a volume for storing a volume of a test system fluid when the test system fluid is under compression.

[0012] In a further exemplary implementation, a method is presented for operating an accelerated cyclic test system for evaluating a valved prosthetic device. A volume of test system fluid is stored in an excess volume area during a system driving stroke that opens the valved prosthetic device. The stored volume of test system fluid is then released during a return stroke that closes the valved prosthetic device.

[0013] This Summary is provided to introduce a selection of concepts in a simplified form that are further described below in the Detailed Description. This Summary is not intended to identify key features or essential features of the claimed subject matter, nor is it intended to be used to limit the scope of the claimed subject matter. A more extensive presentation of features, details, utilities, and advantages of the present invention is provided in the following written description of various embodiments of the invention, illustrated in the accompanying drawings, and defined in the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] FIG. 1 is a combined isometric view and schematic diagram of an exemplary implementation of a fatigue testing system and a corresponding control system.

[0015] FIG. 2A is a front elevation view of the fatigue testing system of FIG. 1.

[0016] FIG. 2B is an enlarged view of the motor support in the area surrounded by the circle labeled 2B in FIG. 2A.

[0017] FIG. 3 is a partial cross sectional view of a test chamber of the fatigue testing system taken along line 3-3 of FIG. 1.

[0018] FIG. 4A is an isometric view in cross section of a portion of the fatigue testing system if FIG. 1 detailing a flexible rolling diaphragm pump connected to a linear piston drive system in a down stroke position.

[0019] FIG. 4B is an isometric view in cross section of a portion of the fatigue testing system if FIG. 1 detailing a flexible rolling diaphragm pump connected to a linear piston drive system in an upstroke position.

[0020] FIG. 5A is an isometric view in cross section of a portion of the test chamber of the fatigue testing system detailing an isolation valve in an open position.

[0021] FIG. 5B is an isometric view in cross section of a portion of the test chamber of the fatigue testing system detailing the isolation valve in a closed position.

[0022] FIG. 6 is a schematic diagram in cross section of an alternative implementation of a test chamber for use in a fatigue testing system.

[0023] FIG. 7 is a graph depicting three exemplary pressure control waves for generation by test control software to provide pressure across a sample device being tested.

[0024] FIG. 8 is a schematic diagram of a software and hardware implementation for controlling a fatigue testing system.

[0025] FIG. 9 is a schematic diagram of an exemplary computer system for controlling a fatigue testing system.

DETAILED DESCRIPTION

[0026] The system of the present invention generally includes a linear actuator or magnetic based drive coupled to a flexible rolling bellows diaphragm to provide variable pressure gradients across test samples mounted in a test chamber housing a fluid reservoir. These components operate together to act as a fluid pump and, when combined with a fluid control system, provide the absolute pressure and/or differential pressure and flow conditions necessary to cycle test prosthetic devices mounted in the test chamber. The flexible rolling diaphragm thrusts toward the lower section of the test chamber to provide a motive force to drive the working fluid through cycles within the test chamber. The flexible diaphragm is coupled to a lower opening in the test chamber and is reciprocally moveable to pressurize and depressurize fluid within the lower section of the main housing. The flexible rolling bellows diaphragm drive system has a very low inertia as compared to other drive systems, e.g., a metal bellows or a standard piston-in-cylinder drive. The flexible diaphragm is highly compliant with low resistance to axial deformation across its entire axial range of motion.

[0027] Plural sample holder tubes are coupled in parallel across the test chamber which has plural fluid distribution channels in communication with each of the sample holders. The lower distribution chamber of the test chamber has a single fluid reservoir in fluid flow communication with each of the plurality of sample holders. The distribution chamber includes a manifold with a plurality of fluid outlet ports, and each fluid outlet port communicates with an inflow opening of a test holder. The upper return chamber of the test chamber includes a similar manifold with a plurality of fluid inflow ports and compliance chambers. Each fluid inflow port communicates with an outflow opening of a respective sample holder. A central return flow channel is provided between the return chamber and the distribution chamber of the test chamber reservoir to provide a return flow of the working fluid from the outflow section of the sample holders. A throttle control and a check valve are disposed at the inflow and outflow ends of the central return flow channel, respectively, to regulate fluid flow during testing. The throttle control serves to partially regulate the pressure across the prosthetic devices being tested as well as the return flow of the working fluid in the fluid test chamber.

[0028] These components operate together to provide a differential pressure and flow conditions necessary to cycle the prosthetic device. The internal conditions, which may include, among other things, temperature, differential pressure, and system pressure, are electrically communicated to monitoring and controlling software on a test system computer. The motion of the fluid pump and therefore the system dynamics are controlled via test system control software. The pressure field resulting from the pump motion is easily controlled and can be set as a simple sine wave or as any complex user created waveform.

[0029] One exemplary implementation of a fatigue testing system 100 for any of a variety of prosthetic devices is depicted in FIGS. 1 through 5B. The fatigue testing system 100 may be understood as having two primary components, a test chamber 106 and a drive motor 105. The fatigue testing system 100 may be both partially mounted upon and housed within a base housing 157 formed and supported by a number of frame members 102. In the implementation shown, the drive motor 105 is housed within the base

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