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NEW TECHNOLOGY REPORT

A Long-Term Ventricular Assist Device Utilizing a Magnetic Bearing System and Implantable Physiologic Controller

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Given the critical shortage of organs available for transplantation in patients with end-stage heart failure, there has been an increasing interest in using currently available ventricular assist devices (VADs) as alternatives to heart transplantation, in addition to using these devices as bridges to heart transplantation. Some of this interest has stemmed from reports of prolonged patient support with VADs such as the HeartMate® device (Thermo Cardiosystems, Inc., Woburn, MA). At our institution, patients have received support with the HeartMate VAD for up to a year before transplantation. Other groups have reported support times as long as three years [McCarthy 1998, Sun 1999]. Cases such as those have in part led to studies such as the REMATCH (Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure) trial, which focuses on using currently available ventricular assist devices as a permanent means of support [Rose 1999].

One of the major concerns with the use of ventricular assist devices as alternatives to transplantation is the question of durability. Currently, most of the available VADs are pulsatile in nature and have had worrisome mechanical problems, such as pneumatic driveline fracture, leakage from valved inflow conduits, and internal pneumatic fracture. Many of these devices also use prosthetic valves that are subjected to significant amounts of stress, which raises further concern over long-term valve durability [McCarthy 1998, Sun 1999]. To overcome these problems, some groups have specifically focused on the development of long-term VADs using valveless, continuous flow pumps. Based on industry experience, these pumps may have a lifetime of 15 years or more.

One issue concerning rotating pumps is the need for appropriate bearings to house the impeller device. Conventional ball bearings cannot be employed in many continuous flow designs because of the risk of hemolysis and thrombosis. To overcome this obstacle, a joint effort by the Utah Artificial Heart Institute and the University of Virginia has developed several continuous flow prototype VADs (HeartQuest system) using very long-life magnetic bearings. These magnetic bearings both suspend and rotate the impeller using a magnetic field. This device has only one moving part and does not require extra valves or other flow adjustment systems that may induce wear, hemolysis, and/or thrombosis. The CF-3 version of this system can generate a continuous cardiac output of 6 L/min while remaining relatively small in size (diameter 10.3 cm, length 3.7 cm) [Anderson 2000]. This device as well as pumps developed by other investigators, including the AB 180, Jarvik 2000, and DeBakey VAD, have undergone successful animal testing. Recently, some of these devices have been successfully implanted into human patients [Savage 1999, Wieselthaler 2000].

Currently, a new HeartQuest model (CF-4) is being developed that is smaller (diameter 7.4 cm, height 3.7 cm; Figure 1, ◎) than the CF-3 device while maintaining similar performance characteristics. Unique to this system is that it will incorporate an automatic feedback controller that adjusts pump flow to meet a wide range of activities. Thus, the device will provide a low level of flow during sleep and a high level of flow during strenuous activities such as climbing stairs or running. The feedback pathways will involve sensors that detect blood pressure fluctuations, respiratory rate, mixed venous oxygen, and movement of the patient. Many of these feedback systems have already been developed for use with pacemakers [Candinas 1997, Celiker 1998]. A pediatric version of the CF-4 device is also being developed for use in children with single ventricle physiology to serve as a right heart device. As this technology

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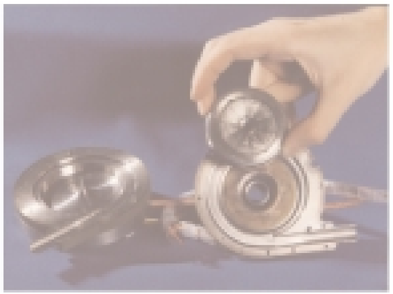

Figure 1.

evolves, these devices may serve as a reliable means of life support and may be capable of automatically adjusting to meet different activity levels or even growth of the patient, further enhancing quality of life.

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