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The Journal of
Heart and Lung
Transplantation

http://www.jhltonline.org

INNOVATION

Optimization of axial-pump pressure sensitivity for a continuous-flow total artificial heart

O. H. Frazier, MD,[a] Hassan A. Khalil, BS,[a] Robert J. Benkowski, BS,[b] and William E. Cohn, MD[a]

From the [a]Department of Cardiovascular Surgery, Texas Heart Institute at St. Luke's Episcopal Hospital, Houston; and [b]MicroMed Technology, Inc., Houston, Texas.

KEYWORDS:
total artificial heart;
blood pump–rotary;
mechanical modeling;
mechanical circulatory support;
perfusion-nonpulsatile

BACKGROUND: In this study, we describe the potential advantages of a continuous-flow total artificial heart (CFTAH) comprising two small, non-pulsatile pumps with optimized responsiveness to the pressure gradient.

METHODS: We modified a MicroMed DeBakey axial-flow pump by increasing its inducer–impeller inlet angle, thereby increasing its pressure responsivity. We obtained the in vitro pressure gradient response and compared it with those of the clinically used, unmodified MicroMed DeBakey pump, Jarvik 2000 FlowMaker and HeartMate II.

RESULTS: The modified pump showed an increased response to changes in the pressure gradient at pump flow rates of between 2 and 4 liters/min. The maximum pressure responsivity of the modified pump was 2.5 liters/min/mm Hg; the corresponding maximum responsivities of the Jarvik 2000, HeartMate II and MicroMed DeBakey ventricular assist devices (VADs) were 0.12, 0.09 and 0.38 liters/min/mm Hg, respectively.

CONCLUSIONS: Because of the inherent properties of non-pulsatile pumps, the CFTAH may potentially respond to changes in inflow and outflow pressures while maintaining physiologic flow rates sufficient for normal daily activity. In addition, the hemodynamic interplay between the two optimized pumps should allow a physiologic response to normal flow imbalances between the pulmonary and systemic circulations. Improved responsiveness to inflow pressure may further simplify and improve the CFTAH and affect its potential clinical use as a meaningful therapy for terminal heart failure.

J Heart Lung Transplant 2010;29:687–91

Although heart transplantation remains the surgical treatment of choice for terminal congestive heart failure, the limitations of donor heart availability, the inherent time-related transplant mortality, the necessity for life-long immunosuppressive therapy, and the convoluted logistics related to immunologic testing, patient selection and organ procurement all underscore the need for the alternative treatments, including mechanical circulatory support. The use of ventricular assist devices (VADs), either as bridges to transplantation or for long-term ventricular support, has increased markedly over the last decade. Several types of VADs have already been approved by the U.S. Food and Drug Administration, whereas others are undergoing clinical trials in North America and Europe. The current generation of VADs includes pulseless axial-flow or centrifugal pumps, which are more durable than their pulsatile counterparts. Clinical success with these pumps[1] has led us to investigate the potential benefit of a novel, continuous-flow total artificial heart (CFTAH) comprising two continuous-flow pumps (CFPs). The device would possess all the benefits of CFPs, including their smaller size, simpler mecha-

Reprint requests: O.H. Frazier, MD, Department of Cardiovascular Surgery, Texas Heart Institute, P.O. Box 20345, MC 3-147, Houston, TX 77225-0345. Telephone: 832-355-3000. Fax: 832-355-6798.

E-mail address: lschwenke@heart.thi.tmc.edu

1053-2498/$ -see front matter
doi:10.1016/j.healun.2009.12.017

nism of operation, fewer moving parts and greater durability. The CFTAH also would be implantable in smaller patients, particularly women and children, who would otherwise be ineligible for larger, pulsatile total heart replacement. Moreover, we believe that the autoregulatory potential of CFPs can be exploited in the CFTAH, allowing automated pump regulation on the basis of venous return (i.e., physiologic requirements), therefore minimizing and perhaps altogether eliminating the need for the external adjustment of pump speed.

Because of the CFTAH's relatively small size and operational simplicity, surgical placement of this system is less complex than implantation of a pulsatile artificial heart. In our laboratories, we have implanted in sheep and calves a variety of CFTAH systems, including those comprising the HeartMate II and HeartMate III (Thoratec Corp., Pleasanton, CA), the MicroMed DeBakey (MicroMed Technology, Inc., Houston, TX), the Jarvik 2000 FlowMaker (Jarvik Heart, New York, NY) and the HeartWare CFP (HeartWare, Ltd., Sydney, Australia).[2,3] For these studies, both ventricles were excised and the inflow cuffs of each pump were sewn to the atrial remnants. (Complete excision of the native heart ensures the non-pulsatile nature of the CFTAH.) More recently, we have enlarged the atrial reservoir with rigid Dacron chambers, thereby protecting against atrial collapse. Even with the larger chambers, the CFTAH is still smaller than a pulsatile artificial heart. Prolonged survival and normal physiologic responses have been demonstrated in experimental animals.[3]

Methods

For the MicroMed DeBakey VAD, the inducer–impeller inlet angle was increased to enhance the pressure responsiveness, similar to that of an airplane's wing at take-off (Figure 1). The pressure–flow relationships of a Jarvik 2000, HeartMate II, MicroMed DeBakey and modified MicroMed pump were measured in a mock circuit, as described elsewhere.[4] The inflow pressure, or pump pre-load, was maintained at 10 mm Hg. The after-load was adjusted by using a screw clamp on the outflow tubing. The outlet pressure was measured with a fluid-filled transducer (Edwards LifeSciences, Irvine, CA) low-pass filtered at 1 Hz (Model 3364; Krohn-Hite, Brockton, MA) and recorded on a computer equipped with a data acquisition board (dSPACE, Inc., Novi, MI) and a ControlDesk graphical user interface (version 2.6.5; dSPACE, Inc.).

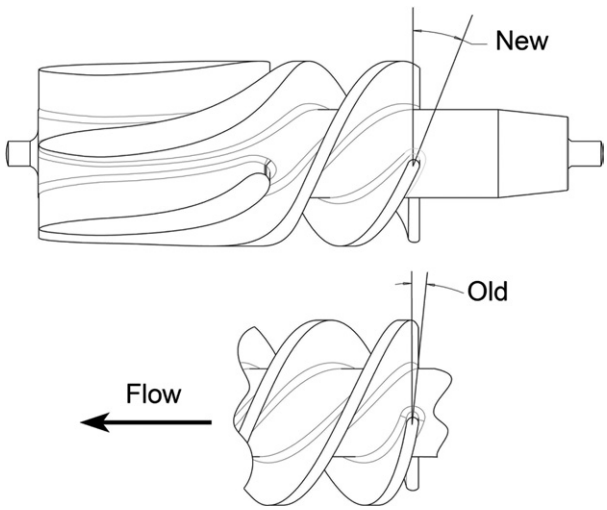

Figure 1 MicroMed pump rotor, illustrating the change in inducer–impeller inlet angle.

Table 1 Range of Pump Speeds Tested

Pump	Speed range (rpm)
Jarvik 2000	8,000–12,000
HeartMate II	7,000–10,600
MicroMed DeBakey	7,500–12,000
Modified MicroMed	6,500–12,000

Flow in both the native heart and the CFPs is determined by the difference (ΔP) between the inflow pressure (pre-load) and the outflow resistance (after-load). Varying either parameter results in a change in the ΔP across the pump and, thereby, a change in pump output. In this approach, we maintained a constant pre-load of 10 mm Hg and changed the ΔP by varying the outflow resistance. The responses of the 4 axial-flow pumps to the varying ΔP were then recorded at flow-rate increments of 0.25 liter/min. Table 1 shows the range of pump speeds tested. For each pump, we plotted the resulting pressure–flow curves for different pump speeds and calculated the pressure sensitivity (change in flow rate ÷ change in ΔP) by using centered, finite-divided differences in Excel (Microsoft, Inc., Redmond, WA).

Results

Figure 2 shows the pump characteristic curves of the Jarvik 2000, the HeartMate II and the clinical and modified MicroMed DeBakey pumps. Tables 2 through 5 show the corresponding calculated pressure responsiveness of these devices. Figure 3 compares the maximum pressure sensitivities of the pumps.

Discussion

Whether the pressure responsiveness of a continuous-flow VAD can be increased to a level compatible with long-term total circulatory support without having to manually alter the pump speed is a topic of intense interest in our laboratory. It has been a long-held hypothesis of the senior investigator (O.H.F.) that design modifications to CFPs could enhance their autoregulatory potential and allow total heart replacement without internal automated speed control in response to patient activity. Current pulsatile TAH re-