ELSEVIER

The Journal of
Heart and Lung
Transplantation

http://www.jhltonline.org

In vivo acute performance of the Cleveland Clinic self-regulating, continuous-flow total artificial heart

Hideyuki Fumoto, MD, David J. Horvath, MSME, Santosh Rao, MD, Alex L. Massiello, MEBME, Tetsuya Horai, MD, Tohru Takaseya, MD, PhD, Yoko Arakawa, MD, Nicole Mielke, BS, Ji-Feng Chen, BS, Raymond Dessoffy, AA, Kiyotaka Fukamachi, MD, PhD, and Leonard A. R. Golding, MB, BS

From the Department of Biomedical Engineering, Lerner Research Institute, Cleveland Clinic, Cleveland, Ohio.

KEYWORDS:
total artificial heart;
continuous-flow;
rotary pump;
hemodynamics;
SVR;
PVR

BACKGROUND: The purpose of this study was to evaluate the acute in vivo pump performance of a unique valveless, sensorless, pulsatile, continuous-flow total artificial heart (CFTAH) that passively self-balances left and right circulations without electronic intervention.

METHODS: The CFTAH was implanted in two calves, with pump and hemodynamic data recorded at baseline over the full range of pump operational speeds (2,000 to 3,000 rpm) in 200-rpm increments, with pulsatility variance, and under a series of induced hemodynamic states created by varying circulating blood volume and systemic and pulmonary vascular resistance (SVR and PVR).

RESULTS: Sixty of the 63 induced hemodynamic states in Case 1 and 73 of 78 states in Case 2 met our design goal of a balanced flow and maximum atrial pressure difference of 10 mm Hg. The correlation of calculated vs measured flow and SVR was high (R^2 = 0.857 and 0.832, respectively), allowing validation of an additional level of automatic active control. By varying the amplitude of sinusoidal modulation of the speed waveform, 9 mm Hg of induced pulmonary and 18 mm Hg of systemic arterial pressure pulsation were achieved.

CONCLUSIONS: These results validated CFTAH self-balancing of left and right circulation, induced arterial flow and pressure pulsatility, accurate calculated flow and SVR parameters, and the performance of an automatic active control mode in an acute, in vivo setting in response to a wide range of imposed physiologic perturbations.

J Heart Lung Transplant 2010;29:21–26

In 1964, the National Institutes of Health established the artificial heart program to promote development of the total artificial heart (TAH) and other cardiac assist devices, due largely to the efforts of the pioneering Dr Michael DeBakey. In 1969, the first implantation of a temporary TAH into a human was done by Dr Denton Cooley.[1] In 1982, Dr William DeVries became the first to implant a permanent TAH (Jarvik-7) into a dying patient.[2] Today, the existing clinical TAH devices—the AbioCor (Abiomed, Danvers, MA) and the CardioWest (SynCardia, Tucson, AZ)[3–7]—are still large, pulsatile devices, preventing their use in many male patients and most female patients. Furthermore, they contain 4 valves with a polymer diaphragm that limit durability and increase the potential for thromboembolic events.

The Cleveland Clinic has developed a unique valveless, sensorless, pulsatile, continuous-flow total artificial heart (CFTAH) that self-balances left and right circulation without electronic intervention. Preliminary results from in vitro mock circulatory loop testing have demonstrated passive

Reprint requests: Leonard A. R. Golding, MB, BS, Department of Biomedical Engineering/ND20, Cleveland Clinic, 9500 Euclid Avenue, Cleveland, OH 44195. Telephone: 216-444-1205. Fax: 216-444-9198.
E-mail address: goldinl@ccf.org

1053-2498/10/$ -see front matter
doi:10.1016/j.healun.2009.05.035

self-regulation of CFTAH flows and atrial pressures while preserving flow and pressure pulsatility by sinusoidal modulation of the speed waveform.[8] The purpose of this corresponding in vivo study was to evaluate the pump performance in an acute setting in response to a wide range of imposed physiologic perturbations to validate its in vitro performance characteristics.

Methods

Configuration and characteristics of the CFTAH

The CFTAH is small at 6 cm in diameter and 10 cm in body length, with a priming volume of 37 ml (Figure 1). As previously described in detail,[8] this design allows for a degree of free axial movement of one moving part (rotating assembly) in the direction of differential forces across the rotating assembly caused by atrial pressure differences. This axial movement changes the opening of an aperture at the outlet diameter (OD) of the right impeller, affecting relative left/right performance in a direction to correct the atrial pressure imbalance. In addition, the CFTAH uses speed modulation to create a simulated cardiac cycle of induced arterial pulsatile flows and pressures that can be used as a potential additional means of physiologic control for the CFTAH. The addition of an automatic speed control mode that responds to sensorless derived physiologic inputs calculates a target pump flow based on sensed systemic vascular resistance (SVR) and implements automatic speed changes to adjust the sensed pump output to match the targeted flow. Also implemented in this control algorithm is an inverse relationship between SVR and the amplitude of speed modulation (±25% of the mean pump speed to a non-pulsatile condition).

The pump is powered through a 3-conductor percutaneous cable to the speed control module, which is powered using a 20-VDC supply. The clinical version will use batteries and/or a power supply. The power consumption is approximately 13 W at 8 liters/min with 20 mm Hg and 80 mm Hg of right and left after-loads, respectively, which generates 11.6 W of heat. About 40% is generated primarily in the stator windings and dissipated by heat transfer from the surface of the stator assembly, which has a very large surface area of 97 square cm. The remaining energy is dissipated directly to the blood via impeller inefficiency and hydrodynamic bearing drag.

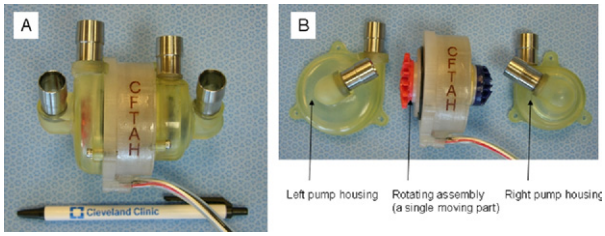

Figure 1 (A) Assembled continuous-flow total artificial heart (CFTAH) and (B) partial disassembly of the CFTAH pump.

Study design and animal model

Two male Holstein calves (91.0 and 100.2 kg) were used for acute studies. The study was approved by the Cleveland Clinic's Institutional Animal Care and Use Committee, and all animals received humane care in compliance with the "Principles of Laboratory Animal Care," formulated by the National Society for Medical Research, and the *Guide for the Care and Use of Laboratory Animals*, prepared by the Institute of Laboratory Animal Resources and published by the National Institutes of Health (NIH Publication No. 86-23, revised 1996).

Surgical procedures

Through a median sternotomy under general anesthesia, cardiopulmonary bypass (CPB) was established after full heparinization (300 IU/kg). Both ventricles were resected at the atrioventricular groove, and inflow cuffs were sutured to the atria. The aorta and the pulmonary artery were anastomosed to outflow grafts. Both chambers of the CFTAH pump were primed with 25% albumin solution with 20 U heparin per cubic centimeter of albumin added, and then they were connected to the inflow and outflow conduits. After both atria and pump housings were de-aired, the CFTAH was started with rapid weaning from CPB. Pump performance was evaluated at baseline after hemodynamic stability was established, followed by the induced hemodynamic states described in what follows.

Hemodynamic analysis of pump performance

The following data were continuously monitored with the chest remaining open: (1) right and left atrial pressure (RAP and LAP) via a fluid-filled catheter on the atrial cuffs; (2) systemic arterial pressure (AoP) via a fluid-filled catheter in the carotid artery or on the left pump outlet graft; (3) pulmonary arterial pressure (PAP) via a fluid-filled catheter on the right pump outflow graft; (4) right and left pump flows via Transonic ultrasonic flow probes; and (5) pump speed motor current from the CFTAH controller. In Case 1, pump flows were measured with 28-mm-diameter ultrasonic perivascular flow probes (Transonic Systems, Inc, Ithaca, NY) placed on the right and left outflow grafts. In Case 2, a Transonic inline flow probe was placed in the left pump inlet pathway and a 28-mm Transonic perivascular flow probe was used on the right pump outlet. Hemodynamic and pump performance parameters were digitized in real time at a sampling rate of 200 Hz with a POWERLAB data acquisition system (ADInstruments, Inc, Mountain View, CA) and stored on a hard disk. The data were analyzed using EXCEL software (Excel 2000, Microsoft Corp, Redmond, WA).