Accuracy of the HVAD Pump Flow Estimation Algorithm

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Controller algorithms are an important feature for assessment of ventricular assist device performance. Flow estimation is one algorithm implemented in the HeartWare continuous-flow ventricular assist device pump system. This parameter estimates flow passing through the pump and is calculated using speed, current, and hematocrit. *In vitro* and *in vivo* studies were conducted to assess the algorithm accuracy. During *in vitro* testing, three pumps were tested in four water–glycerol solutions at 37ºC with viscosities equivalent to hematocrits of 20, 30, 40, and 50%. By using a linear regression model, a correlation coefficient of >0.94 was observed between measured and estimated flow for all conditions. *In vivo* studies (n = 9) were conducted in an ovine model where a reference flow probe was placed on the outflow graft and speed was adjusted from 1,800 to 4,000 revolutions per minute. During *in vivo* experiments, estimated pump flow (mean, minimum, and maximum) was compared with measured pump flow. The best-fit linear regression equation for the data is $y = 0.96x + 0.54$, $r^2 = 0.92$. In addition, waveform fidelity was high ($r^2 > 0.96$) in normal (*i.e.*, nonsuction) cases where flow pulsatility was >2 L/min. The flow estimation algorithm demonstrated strong agreement with measured flow, both when analyzing average waveform magnitude and fidelity. *ASAIO Journal* 2016; 62:15–19.

Key Words: flow estimation, HVAD pump

Ventricular assist device (VAD) flow is a key parameter for managing patients undergoing mechanical circulatory support.[1] For this reason, some VADs incorporate sensors for direct measurement of pump flow.[2] Limitations of implantable sensor technologies are that they increase overall system cost and complexity while reducing long-term reliability.[3–5] In lieu of implantable sensors, other devices have opted to estimate pump flow by algorithms based on other parameters of pump function, particularly power consumption.[6,7] Several studies were conducted to assess the accuracy of these algorithms, which concluded that the flow estimation algorithms are valuable as trending tools, but not for accurate measurement of absolute flow values.[6,8,9] A study by Giridharan *et al*.[10] analyzed flow estimation accuracy of the HeartWare continuous-flow ventricular assist device (HVAD) pump (HeartWare, Inc., Miami Lakes, FL) in a static mock loop with glycerol–water mixtures at three viscosities, reporting flow estimation errors of ± 0.5 L/min at 2.7 cP, ± 0.2 L/min at 3.2 cP, and ± 0.5 L/min at 3.7 cP. It should be noted that no study has yet reported on the accuracy of flow estimation of the HVAD pump in *in vivo* pulsatile environment or analyzed accuracy of waveform average, minimum, maximum, and fidelity.

The HVAD pump is a continuous-flow, centrifugal VAD implanted in patients with end-stage heart failure. The device is implanted inside the thorax with the inflow cannula inserted into the ventricle and the outflow graft anastomosed to the arterial vasculature. The HVAD pump utilizes a wireless hybrid hydromagnetic impeller suspension system. The rotational speed of the impeller ranges from 1,800 to 4,000 revolutions per minute (RPM) and can support flows of up to 10 L/min. The percutaneous driveline connects the pump to an external controller that serves to power, control, monitor, and log pump operation.[11] Further description of the HVAD pump system is provided by LaRose *et al*.[12]

HVAD Flow Estimation Algorithm Description

The HVAD flow estimation algorithm has three inputs and two outputs. The input parameters consist of pump rotational speed, pump current, and the patient's hematocrit. Clinicians are able to adjust two of these inputs, the rotational speed and hematocrit setting, through the system monitor. The output parameters consist of an instantaneous pump flow signal and average pump flow. The waveform is displayed in real time on the monitor along with the average value.

The relationship between electrical current drawn by the pump (I) and blood flow through the pump (Q) is the basis for the HVAD flow estimation algorithm. These I-Q curves characterize the pump performance over the physiological range of pump speeds, pump flows, and blood viscosities. The valid range of estimated flow with the HVAD controller is between −2.0 and +10.0 L/min. In addition, HVAD pump I-Q curves are characterized for normal (dual motor stator operation) and also for single stator operation (front motor or rear motor). The latter allows the estimation of pump flow even when one motor stator fails, such as when there is a damage to the pump driveline. I-Q curves are programmed into the controller software in the form of tables that are interpolated to create the real-time flow estimation waveforms as shown schematically in **Figure 1**.

Methods

In Vitro *Testing*

In vitro studies were performed in a simple, steady-state flow loop with a water–glycerol solution at 37ºC. Four hematocrits: 20, 30, 40, and 50% were simulated through adjustments to fluid viscosity. The conversion between target hematocrit and viscosity was approximated by Guyton *et al*.[13] A Brookfield viscometer (Model LVDV-II+P CP; Brookfield Engineering

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Submitted for consideration April 2015; accepted for publication in revised form September 2015.

Disclosure: All authors are employees of HeartWare, Inc.

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DOI: 10.1097/MAT.0000000000000295

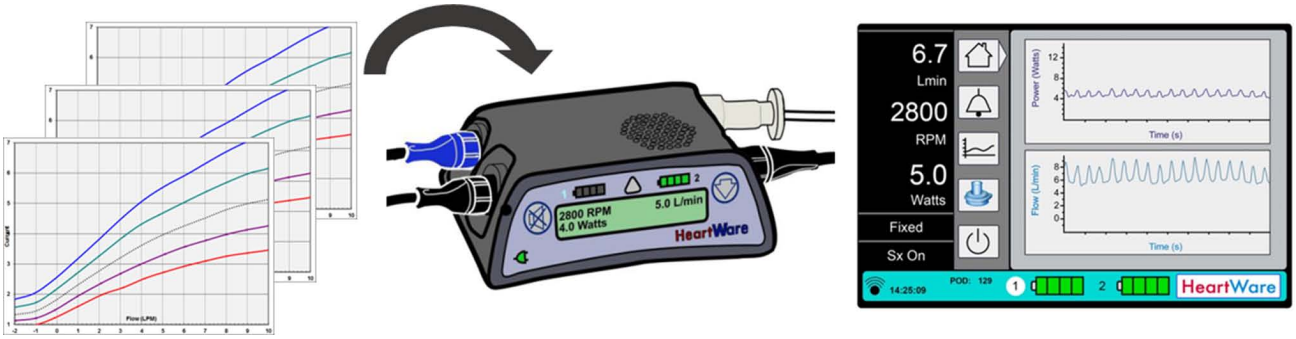

Figure 1. I-Q curves are the basis for the flow estimation algorithm and are programmed into the HeartWare continuous-flow ventricular assist device pump controller. These curves are used to calculate the flow waveform for a particular speed, hematocrit, and current reading.

Laboratories, Middleborough, MA) was used to measure fluid viscosity. In these experiments, simulated hematocrits of 20, 30, 40, and 50% had measured viscosities of 1.9 ± 0.2, 2.3 ± 0.1, 3.4 ± 0.3, and 5.0 ± 0.1 cP, respectively.

The HVAD pump was connected in series to a turbine flow probe (Flow Technology, Tempe, AZ) whose accuracy is independent of fluid temperature and viscosity. Controller hematocrit settings were set to match the test conditions using the system monitor. Pump speed was increased from 1,800 to 4,000 RPM in increments of 200 RPM for each hematocrit. In addition, to provide different hemodynamic operating conditions, the pump outflow was tested in both an unrestricted and a semirestricted state. In the semirestricted state, a side clamp was applied 3.0 cm away from the pump outlet to reduce the standard 10 mm diameter by 20, 30, 40, and 50%. A pin gauge was used to confirm the restricted diameter. This outflow restriction was applied for a distance of 3.5 cm.[14] Three trials were performed using a total of three (n = 3) HVAD pumps to assess repeatability. Flow estimation error was calculated by computing the absolute difference between estimated pump flow and measured pump flow at each test condition.

In Vivo *Testing*

In vivo studies were performed in an acute ovine model to compare HVAD estimated flow with flow measured directly by the flow probe. Testing was conducted in nine (n = 9) healthy Suffolk Cross sheep weighing 68.4 ± 3.1 kg. 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). The pump was implanted without the use of cardiopulmonary bypass. The inflow cannula for the HVAD pump was inserted into the left ventricular apex, and the 10 mm Dacron outflow graft was anastomosed to the descending aorta in an end-to-side fashion. A transit-time ultrasonic flow probe (Transonic Systems, Ithaca, NY) was placed around the pump outflow graft. Before the experiment, this flow probe had been specifically calibrated by the manufacturer for this graft size and type. Once the pump was implanted, speed was initiated at 1,800 RPM. A blood sample was collected to determine hematocrit at the time of measurements, and the results were input to the HVAD system monitor. Pump speed was then increased from 1,800 to 4,000 RPM in increments of 200 RPM. Each speed was maintained for approximately 2 minutes to obtain a steady-state condition. The speed ramp was discontinued if significant episodes of pump suction were observed. Herein, we define the occurrence of suction as intermittent negative deflections in the measured flow waveform that exceed a 2.0 L/min decrease in magnitude.

Real-time data from the HVAD controller and flow probe were collected using a custom data acquisition (DAQ) system, which was developed on a LabVIEW platform (National Instruments, Austin, TX). The sampling rate for this DAQ system was set to 50 Hz to match controller output.

Data were analyzed using a custom software viewer developed on a LabVIEW platform (National Instruments Corporation, Austin, TX). Estimated pump flow was compared with measured pump flow by examining a 10 second window at each pump speed and comparing the mean, maximum, and minimum of the two signals. Flow estimation error was calculated by computing the absolute difference between the mean estimated pump flow and the mean measured pump flow at each test condition. The average and standard deviation of the absolute mean flow estimation error was then calculated. Waveform fidelity was also examined by calculating the correlation coefficient between the estimated flow and the measured flow. A phase shift was observed between the measured and the estimated flow signals, so this phase shift was adjusted to obtain a maximum correlation coefficient value.

Results

In Vitro *Studies*

Both *in vitro* and *in vivo* testing demonstrated strong agreement between measured pump flow and estimated pump flow using a linear regression model. Results from the flow loop experiments, in which flows ranged between 1.4 and 7.0 L/min, showed >0.94 correlation coefficient between the measured turbine flow and the estimated pump flow for all hematocrit settings tested (20–50%) as well as all outflow restrictions tested (0–50%; **Figure 2**). Average flow errors for each test condition were <1.0 liter per minute as summarized in **Table 1**.

In Vivo *Studies*

Hematocrit values ranged between 18% and 35% during the nine *in vivo* studies. Maximum pump speeds achieved averaged 3,354 ± 312 RPM at which point flow averaged 4.1 ± 1.1 L/min.

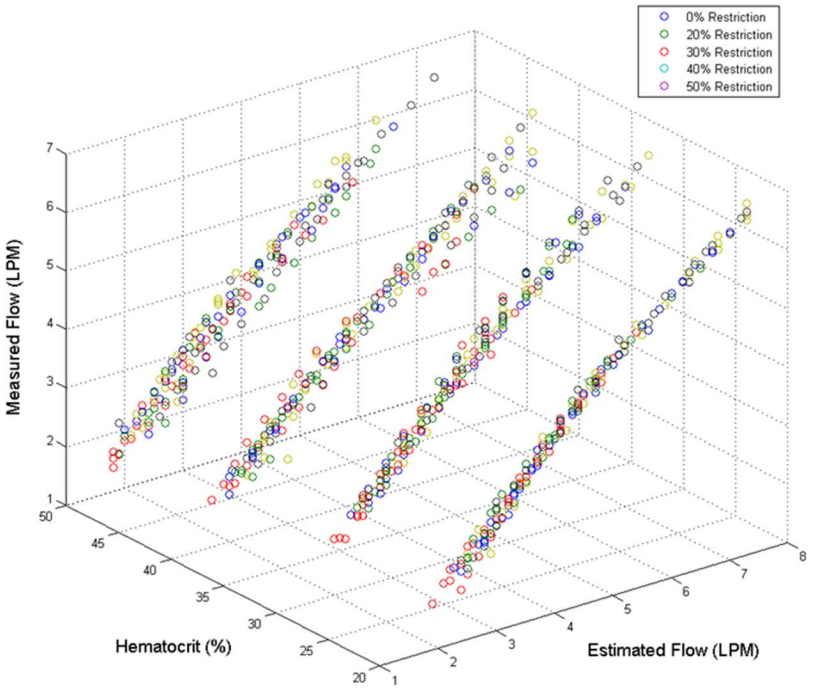

Figure 2. Correlation between measured turbine flow and estimated HeartWare continuous-flow ventricular assist device pump flow are shown for four viscosities (20%, 30%, 40%, and 50%) and five outflow restriction states during *in vitro* testing. Correlation coefficient values for all test conditions were >0.94. LPM, liter per minute.

Suction occurred in three of the nine trials (each time at speeds >3,200 RPM).

Signal fidelity between the estimated flow waveform and the measured flow waveform was analyzed to determine the similarity of waveform shapes. A phase shift of 0.02 ± 0.01 seconds was applied to account for differences in processing time between the two flow signals. Examples showing the concordance between simultaneous real-time HVAD flow estimated signals and those provided by high-resolution transit-time flow probe are shown in **Figure 3**. A typical normal waveform morphology with flow ranging between 2 and 5 L/min (with a pulsatility of ~3 L/min) is shown in **Figure 3A**. An example with very low pulsatility (as may occur with low ventricular preload and high pump speeds) is shown in **Figure 3B**. An example showing intermittent suction events is shown in **Figure 3C**. These curves are characterized by sharp, transient, negative deflections in flow.

Table 1. Average of the Flow Estimation Algorithm's Absolute Error (± Standard Deviation) When Compared Against Measured Pump Flow During *In Vitro* Testing for Three HVAD Pumps (n = 3)

	Hematocrit (%)			
Restriction (%)	20	30	40	50
0	0.2 ± 0.2	0.2 ± 0.2	0.4 ± 0.3	0.2 ± 0.1
20	0.2 ± 0.1	0.2 ± 0.2	0.3 ± 0.3	0.5 ± 0.3
30	0.1 ± 0.1	0.2 ± 0.1	0.3 ± 0.3	0.3 ± 0.3
40	0.1 ± 0.1	0.2 ± 0.1	0.3 ± 0.4	0.5 ± 0.3
50	0.1 ± 0.1	0.2 ± 0.1	0.3 ± 0.3	0.3 ± 0.2

Data are represented as liter per minute.
HVAD, HeartWare continuous-flow ventricular assist device.

To facilitate comparisons, flow waveforms were quantified by their maximum (peak), minimum (trough), and mean values. There was a linear correlation for each of these values between measured and estimated flow signals as shown in **Figure 4**. This plot includes data from all animals and all speeds investigated and thus included waveforms with characteristics spanning the spectrum summarized in **Figure 3**. Analysis confirmed a high correlation between direct and estimated flow with linear regression line that did not differ appreciably from the line of identity: $y = 0.96x + 0.54$, $r^2 = 0.92$. Strong agreement was present for the minimum flow values, the maximum flow values, and the mean flows values. The average absolute flow estimation error for mean flow values was 0.5 ± 0.3 L/min.

Accordingly, there was an equally strong agreement between pulsatility (*i.e.*, maximum – minimum flow) from the flow probe and from the flow estimator (**Figure 5**): $y = 0.93x + 0.25$ L/min, $r^2 = 0.88$. In this figure, the suction data points are differentiated from the normal data points. It was observed that measured flow reported larger decreases in pump flow during suction events than what was reported by the flow estimation algorithm. This is summarized quantitatively in **Figure 6**, which shows the correlation coefficient as a function of flow pulsatility. High correlation coefficients ($r^2 > 0.96$) were observed for normal waveforms with pulsatility >2 L/min. For waveforms with pulsatility <2 L/min, the waveform correlation coefficients were lower ($0.51 < r^2 < 0.96$). Suction data points also showed comparatively lower correlation coefficient values ($0.66 < r^2 < 0.88$). This was the result of filtering by the flow estimation algorithm, which blunts the rapid drop in flow. However, as seen in **Figure 3C**, the estimated flow waveforms for suction cases are still a good overall representation of measured waveform shape for clinician purposes.

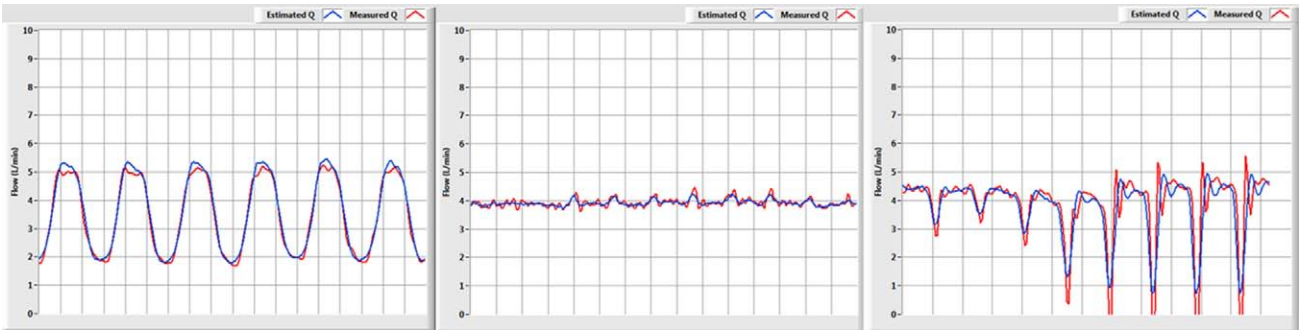

Figure 3. A: Normal waveforms with pulsatility >2 L/min had high correlation with the measured flow signal during *in vivo* testing, whereas low pulsatility (<2 L/min) waveforms (**B**) and suction waveforms (**C**) had lower correlation.

Discussion

The measured and estimated pump flow signal were in strong agreement and provided equivalent values for peak, trough, and mean values during both the *in vitro* and the *in vivo* studies. For *in vitro* studies, the average of the flow estimation algorithm's absolute error for any test condition was at most 0.5 ± 0.3 L/min. This was observed at a 50% hematocrit and restrictions of 20 and 40%. Similarly, *in vivo* studies showed that the average of the flow estimation algorithm's absolute error was 0.5 ± 0.3 L/min for mean values. Although a phase shift was observed that required postprocessing to achieve signal alignment, it is important to note that this did not impact calculations of the waveform mean, minimum, and maximum.

Analysis of signal fidelity demonstrated that estimated pump flow is a good indicator of real-time waveform shape with high correlation coefficients ($r^2 > 0.96$) observed for normal waveforms with pulsatility >2 L/min. However, some rapid, transient events such as suction or low pulsatility (<2 L/min) may be filtered, resulting in a lower correlation coefficient value. It may be possible to improve algorithm accuracy even further by addressing the signal's higher frequency content.

This study had several limitations that should be discussed. As a result of the selected animal model, higher flow rates (>7 L/min) and hematocrit ranges as may be encountered in patients could not be tested in these set of experiments. The highest average pump flow achieved was 6.9 L/min with a waveform peak of 8.7 L/min. As a result of the implantation procedure, the highest hematocrit tested was 35%. Future experiments should test these higher physiologic limits, which are within the expected clinical range. Additional validation in patients would further bolster the conclusions.

Another limitation in this study was the accuracy of the reference flow probe, which reports an absolute accuracy of ±10%. Thus, the inherent error present with the measured flow signal should be taken into consideration. Also, when comparing the two signals, a phase shift was observed because of differing processing times by the flow probe/flowmeter console, controller hardware, and DAQ system. Further characterization of this signal latency may be useful for future experiments.

Conclusion

A noninvasive and accurate pump flow indicator is an important tool for VAD patient management. In these experiments, the HVAD pump system demonstrated excellent agreement between measured pump flow and estimated pump flow, both when analyzing average waveform magnitude (mean, minimum, and maximum) and waveform fidelity. These results lay the foundation for the development and testing of

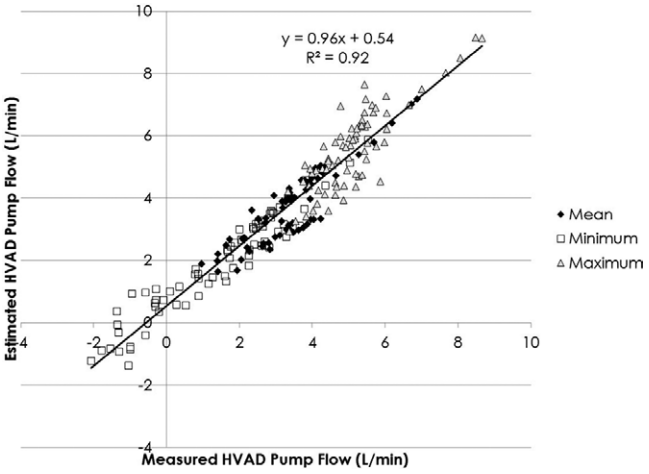

Figure 4. Comparison between estimated pump flow and measured pump flow during *in vivo* testing with linear regression equation and correlation coefficient shown. HVAD, HeartWare continuous-flow ventricular assist device.

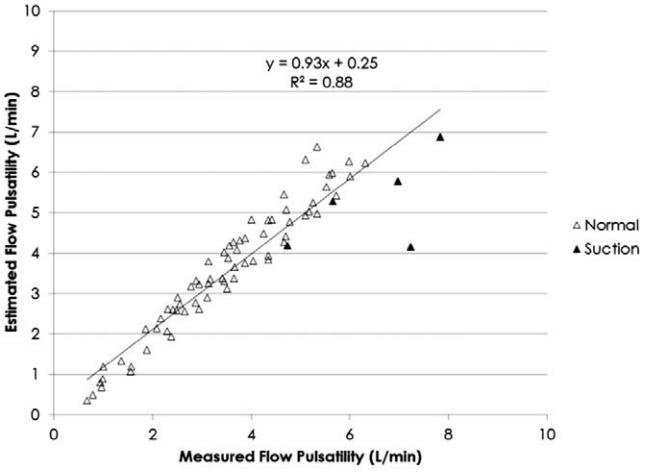

Figure 5. Comparison between pulsatility levels of estimated pump flow and measured pump flow during *in vivo* testing with linear regression equation and correlation coefficient shown.

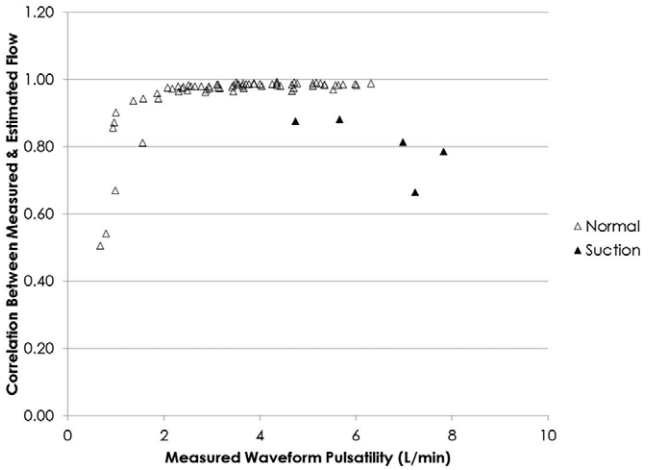

Figure 6. Waveform correlation coefficient during *in vivo* testing is shown as a function of measured waveform pulsatility, where suction points are differentiated from normal points.

new algorithms that, in turn, rely on the accurate noninvasive estimation of pump flow signals. For example, HVAD pump algorithms to assess ventricular contractility and left ventricular end-diastolic pressures using features of the estimated real-time flow waveform signals have already been proposed and tested.[15] Such algorithms offer the possibility to provide clinicians with additional information for guiding management.

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