Published in final edited form as:

ASAIO J. 2015 ; 61(6): 726–728. doi:10.1097/MAT.0000000000000263.

Sensorless Suction Recognition in the Self-Regulating Cleveland Clinic Continuous-Flow Total Artificial Heart

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Abstract

The Cleveland Clinic continuous-flow total artificial heart passively regulates itself in regard to the relative performance of systemic and pulmonary pumps. The system incorporates real-time monitoring to detect any indication of incipient left or right suction as input for automatic controller response. To recognize suction, the external controller compares the waveforms of modulating speed input and power feedback. Deviations in periodic waveforms indicate sudden changes to flow impedance, which are characteristic of suction events as the pump speed is modulating. Incipient suction is indicated within three seconds of being detected in the power wave form, allowing timely controller response before mean flow is affected. This article describes the results obtained from subjecting the system to severe hemodynamic manipulation during an acute study in a calf.

Keywords

Hemodynamics; waveform; Heart-assist devices

Introduction

The blockage of one or more ports of a total artificial heart represents a critical patient hazard. Inlet blockage due to suction is caused by pump output exceeding blood supply, as a result of hypovolemia. Sensing the onset of suction in real time allows the immediate corrective action of decrementing speed to avoid a reduction in mean flow. This article describes two real-time suction-recognition schemes, demonstrated by subjecting the system to severe hypovolemic excursions during an acute experiment in a calf, implanted with a continuous flow total artificial heart.

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Conflicts of Interest

David Horvath, Leonard A.R. Golding, and Barry Kuban are inventors. The technology was licensed to Cleveland Heart, Inc., a Cleveland Clinic spin-off company. If this total artificial heart is successful, the inventors and Cleveland Clinic may benefit.

The Cleveland Clinic continuous-flow total artificial heart (CFTAH),¹⁻⁴ delivers blood flow to both the systemic and pulmonary circulation from a single pump assembly (one motor with one rotating assembly supported on a hydrodynamic bearing). Impellers supporting the left and right circulation are mounted on opposing ends of the rotating assembly, which is free to move axially. The left and right hydraulic environments create opposing forces at opposite ends of the assembly, opening and closing an aperture at the output of the right impeller, allowing passive self-regulation of the relative performance of the left and right pumps to balance atrial pressures.

Suction Recognition Methods

We investigated two different methods for recognition of incipient suction, based on comparison of the sinusoidal speed input signal to the power output signals. During normal operation, the pump's motor is the only tangible forcing function in the system, so the speed input and flow output have similar waveforms. Since normalized current (current divided by pump speed squared, A/krpm²) is linear with flow, the normalized current waveform is also similar to the speed waveform. Although the use of a sinusoidal speed input is not required, it greatly simplifies signal processing. The first indication of suction occurs when the pump is reaching peak speed, momentarily impeding the flow and altering the current signal, causing them to deviate from a sine wave.

Method 1

Motor current is a function of speed and flow, and without obstruction, the power and flow will rise and fall with speed. The controller fits the normalized current of the previous 3 seconds to an arbitrary sine wave function, with constants A1 through A3 determined by real-time linear regression, to match the actual normalized current waveform.

$$\text{Normalized Current Function (NCF)} = A1 + A2 \cdot \sin(\omega t) + A3 \cdot \cos(\omega t) \quad (1)$$

where ω = speed modulation frequency (radians per second) and t = seconds.

A sudden change in the waveform is indicated by a standard error in the linear regression of the last three seconds of power vs. speed data. A trigger value in the standard error causes the system to recognize suction.

Method 2

A second method uses the area of the hysteresis loop formed by the dynamic relationship between normalized power (power divided by pump speed squared, W/krpm²) and speed. Since normalized power is directly related to flow, this hysteresis loop is analogous to a flow vs. speed relationship. At the start of suction, the area of the normalized power vs. speed hysteresis loop changes in shape and increases in area as fluid availability periodically diminishes as a result of the reduction in peak modulating flows.

The normalized power is integrated once per second with respect to speed over an integer number of speed cycles within the previous 3-s data cycle. The resulting area is normalized

by dividing by speed range, resulting in the integrated suction parameter (ISP), which is compared to a trigger value.

$$ISP = \frac{\int_{t=0}^{3\text{sec}} \frac{P(t)}{N(t)^2} dN}{N_{\text{max}} - N_{\text{min}}} \quad \text{W/krpm}^2$$

where $P(t)$ = used power (W), $N(t)$ = pump speed (krpm), and used power (W) = total motor power – power with impellers removed (bearing-related losses determined at pump bench calibration).

The speed modulation rate (beats per minute, bpm) is set to 60, 80, 100, or 120 bpm (80 bpm used for these tests), such that there is an integer number ($n = 3, 4, 5$ or 6) of speed-modulation cycles over the 3-s integration period.

Results

Figure 1 presents a comparison of speed and normalized current waveforms during normal operation (Method 1). The speed and current are monitored in the controller, and the normalized current is fit using a least-squares algorithm to an arbitrary sine wave equation (NCF, Eq 1.). The standard error in the fit is very low (0.0008 A/krpm^2) indicating that the normalized current and speed waveforms are similar. Figure 2 presents an indication of suction. As peak speed is reached, the sinusoidal flow and normalized current are momentarily impeded, resulting in a recognizable standard error (0.0025 A/krpm^2) in the linear regression fit. The controller has a manually entered threshold value for the standard error, and that value can trigger a warning message and decrement in speed.

The hysteresis loop in Method 2 (Figure 3) enlarges as suction starts (Figure 4), with the flow periodically dropping for a moment at peak speed, and is displayed on the system interface, providing a real-time visual as well as calculated automatic indication of suction. The ISP values increased from 0.46 to 0.77 W/krpm^2 as the suction condition is introduced.

Discussion

The foregoing algorithms demonstrate methods being used to identify, in real time, any incipient suction affecting the implanted CFTAH. These methods reside solely in the controller software without any sensors. The onset of suction is identified by an interruption in the sinusoidal response to a sinusoidal speed input.

The fundamental limitation is that these suction recognition concepts are not useful without the subsequent development of a reliable suction avoidance system. This larger remaining field of effort will determine how to use these methods to mitigate risks to patients, minimize false positive readings, and still reliably respond to the onset of suction by safely decrementing pump speed. For example, if the system is too sensitive, secondary forcing functions (sneezing, coughing, hiccups, Valsalva maneuver) might trigger false positives

Conclusion

The external controller recognizes the onset of suction by real-time comparison of the output power signal waveform to the input modulating speed waveform. A sinusoidal speed input is used to simplify signal analysis. Use of a sinusoidal speed input greatly simplifies signal analysis.

Acknowledgments

Source of Funding

This work was supported with funding obtained from the National Heart, Lung and Blood Institute under Grant 5R01HL096619 (to LARG and KF).

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NCF = Sinusoidal Curve Fit Over 3 Sec of Data @ 100 HZ

Figure 1.
Normalized current signal – Example indication of no suction.

NCF = Sinusoidal Curve Fit Over 3 Sec of Data @ 100 HZ

Figure 2.
Normalized current signal – Example indication of suction

Figure 3.
Normalized power vs. speed characteristic for no suction condition.

Figure 4.
Normalized power vs. speed characteristic for suction condition.