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Noninvasive Predictor of HeartMate XVE Pump Failure by Neural Network and Waveform Analysis

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Patients increasingly require longer durations of left ventricular assist device (LVAD) therapy. Despite a recent trend toward continuous flow VADs, the HeartMate XVE is still commonly used, but its longevity remains a significant limitation. Existing surveillance methods of pump failure often give inconclusive results. XVE electrical current waveforms were collected regularly (2001–2008) and sorted into quartiles according to number of days until pump failure (Q_1, 0–34; Q_2, 34–160; Q_3, 160–300; and Q_4, 300–390 days). Thoratec waveform files were converted into text files. The 10-second electrical current, voltage waveform was identified and isolated for analysis. Waveforms were analyzed by principal component analysis (PCA) and with a fast Fourier transform. Quartiles were compared with analysis of variance (ANOVA). Waveforms (n = 454) were collected for 21 patients with failed pumps. An artificial neural network was used to predict pump failure within 30 days from the waveform characteristics identified though signal processing. *ASAIO Journal* 2010; 56:1–5.

Left ventricular assist devices (LVADs) are a viable treatment for selected patients with end-stage heart failure. Individuals who receive LVADs are most frequently classified into one of two therapies: bridge-to-transplant (BTT) or destination therapy (DT). Bridge-to-transplant patients may have an LVAD for as little as 1 month, whereas DT patients are implanted until their end of life. Because of the growing shortage of available organ donors, BTT patients may wait for several years for an available heart after their LVAD implantation. Destination therapy patients may live for 1–6 years after their implant. Patients are implanted with either a pulsatile pump similar to Thoratec HeartMate XVE (XVE) or a rotary pump such as the Thoratec HeartMate II (HMII). While rotary pumps are built to last >5 years, the majority is still in clinical trials, which limits the number of patients who are able to receive a rotary pump.[1] Despite a recent trend toward continuous flow LVADs, the HeartMate XVE is still being implanted: 26 have been implanted during the first 5 months of 2009. As of June 2009, there were ~29 of 124 patients still supported by the HeartMate XVE in the HMII trial. Because many of the XVE devices are beginning to show signs of failure, methods must be developed to predict pump failure so that elective replacements can be planned before catastrophic pump failure occurs. The XVE is currently the only LVAD that is Food and Drug Administration (FDA) approved for DT, making it available to more people. However, its longevity remains a significant limitation; the XVE commonly fails because of bearing wear after a period of 1.5 years.[2]

Because of the long durations that a patient may be supported by an LVAD, prediction of when the XVE will near its end-of-life is essential.[3,4] Understanding that when a pump will fail is necessary to allow time for clinicians to prepare for the appropriate course of action and limit the number of unexpected catastrophic pump failures.[5] Existing technology uses a combination of electrical current waveforms, which are visually inspected by Thoratec representatives, and vent filters, which collect machine dust from the pump, to predict pump failure.[6] Unfortunately, these methods to identify pump failure often end with inconclusive results. Patients, particularly DT patients, may live hours from the hospital. By using current methods of pump failure identification, it is difficult to justify bringing the patient closer to the hospital for close supervision of their pump.

The purpose of this study is to identify signs and indications of XVE pump failure from the electrical current waveform. In addition, this study characterizes XVE pumps and identifies whether a pump with its associated waveform is within 30 days of complete mechanical pump failure.

Patients and Methods

Patient Population

The VE/XVE has been used for a period of 14 years at the Utah Artificial Heart Program. In this study, we identified patients whose pumps were known to have failed. We defined pump failure to be the necessity of the pump to be pneumatically driven for support to continue. This occurs when the electronic motor is no longer able to keep the patient hemodynamically stable. General patient characteristics were identified.

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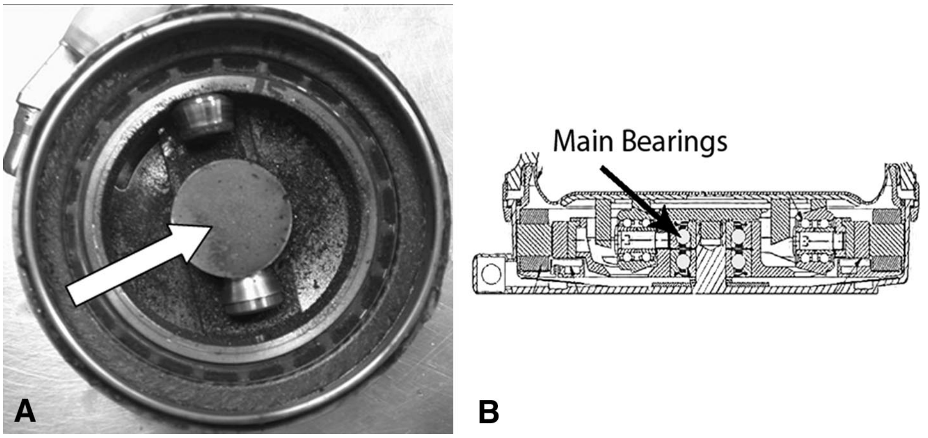

Figure 1. A: Image of a failed HeartMate XVE. The white arrow is pointing to the main bearing housing. The dust is caused from the main bearing rubbing on the pump housing. **B:** Schematic of the HeartMate XVE. The arrow is pointing to the main bearings.

Waveform Analysis

Waveforms were retrospectively analyzed from XVE pumps at various stages of the pump's duration, during scheduled clinic visits, and during times of adverse events. The waveforms obtained were evenly split into quartiles according to the time prefailure the waveform was obtained. Signal processing methods were used to identify and quantify waveform characteristics of each pump at various time periods before pump failure.

Electrical current waveforms were collected for each patient. The Thoratec HeartMate XVE is a cam driven pump (**Figure 1A**). The main bearings are located in the center of the pump (**Figure 1B**). The main bearing endures the force of each cycle of the pump and, thus, is most susceptible to wear.

The clinical system monitor for the XVE allows for collection of pump parameters and waveforms in the form of ".TCI" files. A .TCI file obtained from the system monitor contains two one-cycle waveforms and a 10-second waveform. All waveforms indicate the current and voltage used by the XVE motor. The .TCI files were collected at regular intervals throughout the support duration of each patient. Specifically, .TCI files were collected during scheduled clinic visits or when there was a suspected issue with the pump between 2001 and 2008.

Because the waveforms were in Thorectc's proprietary .TCI file format, initial preprocessing of the .TCI files was necessary. The .TCI files were converted into usable American Standard Code for Information Interchange (ASCII) files by a program written in C^{++}. Both the one-cycle and 10-second waveforms were obtained. The waveforms were then organized into a database for analysis.

Initially each 10-second waveform was processed, and the mean current and voltage was identified. The first 300 msec of each waveform was projected onto the full 10-second waveform. The peaks from the resulting array were found and averaged, resulting in a current projection coefficient and a voltage projection coefficient. The one-cycle waveform was also processed, and the mean current for the 30 msec near the end of the current signal was identified.

A fast Fourier transform (FFT) was used to transform the 10-second current waveforms from the time domain into the frequency domain. It was necessary to look at all of the waveforms in the frequency domain, because a direct comparison in the time domain was impossible. Once a signal was in the frequency domain the magnitude of the 60–80 Hz range was used for further analysis.

Principal component analysis (PCA) was used to characterize current waveforms transformed into the frequency domain.[7] Principal component analysis is Eigenvector-based multivariate analysis. The first 20 Eigenvalues and Eigenvectors of a covariance matrix, created from waveforms transformed into the frequency domain, were found. The Eigenvectors were then used to find a descriptive coefficient for each individual waveform by projecting the waveform onto the Eigenvector. The projection was taken for every pump and associated waveform in our database. After the Eigen projection coefficients were found, the waveforms were organized according to days before failure, and trends were identified.

The signal characteristics aforementioned were found for each waveform using a custom Matlab function. The resulting waveform characteristics were used to predict whether the pump would fail within the next 0–30 days.

Statistical Analysis

Analysis by artificial neural networks (ANNs) was used to classify each signal based on waveform characteristics resulting in a pump failure prediction model. A feed-forward multilayer perceptron ANN model was used and built in MatLab (MathWorks, Inc., Natick, MA). Inputs to the model comprised values obtained from the electrical current, the voltage, the frequency signal, and the Eigen projection coefficients. All of the input values were standardized. The ANN training set comprising 320 randomly assigned waveforms was used to create the prediction model. Training was done by using a backpropagation learning algorithm. One hundred twenty-five waveforms were used for model validation.

Comparisons of basic descriptive statistics of waveforms for patients supported with the XVE were performed using paired Student's t tests as appropriate. Quartiles were compared with analysis of variance (ANOVA) and *post hoc* analysis with Tukey. A comparison with a p-value of <0.05 was considered significant. SPSS version 15 (SPSS, Inc., Chicago, IL) for windows XP was used for statistical analysis.

Table 1. Patient Characteristics (n = 20)

Age (yr)	62 ± 16.05
BTT:DT	1:19
Support duration (d)	579 ± 178.19
Male:female	18:2
VE:XVE	1:19
Pump replacement	70%

BTT, bridge to transplant; DT, destination therapy; XVE, Thoratec HeartMate XVE.

Results

Patients' Characteristics

Four hundred fifty-four waveforms were collected between 2001 and 2008 for 20 pumps. Patient characteristics associated with each device are described in **Table 1**. The quartiles were Q_1 (0–34 days, n = 110), Q_2 (34–160 days, n = 116), Q_3 (160–300 days, n = 112), and Q_4 (300–905 days, n = 116).

Waveform Characteristics

On analysis of the waveforms, it was determined that the center portion contained significant information about the average current (**Figure 2**). For each quartile, we analyzed the mean current for a 30-msec portion of the signal taken from the center of the signal (**Figure 3**). Q_1 had a significantly higher average current, with *p*-value >0.001.

We analyzed the 10-second waveforms from the .TCI file in the frequency domain. We focused on the frequency range of 60–80 Hz (**Figure 4**). There was a significant difference in the amount of energy observed between Q_1 and Q_{2-4} ($p < 0.001$).

By using the method of PCA, we were able to characterize the waveform of any single pump with the use of Eigen projection coefficients. The first Eigenvector was identified as containing a generalized signal for the XVE. Eigenvectors 2–20 proved to be difficult to interpret. All 20 Eigenvectors proved to be useful factors in the prediction model.

Artificial Neural Network

A neural network model was developed, which comprised five artificial neurons in the hidden layer (**Figure 5**). After training, the model was 93% accurate at predicting whether a pump would fail within 30 days. A blind testing set of data were then used to validate the model. The testing set was 93% accurate at predicting pump failure within 0–30 days (**Table 2**). The area under the receiver operating characteristic (ROC) curve was 0.971.

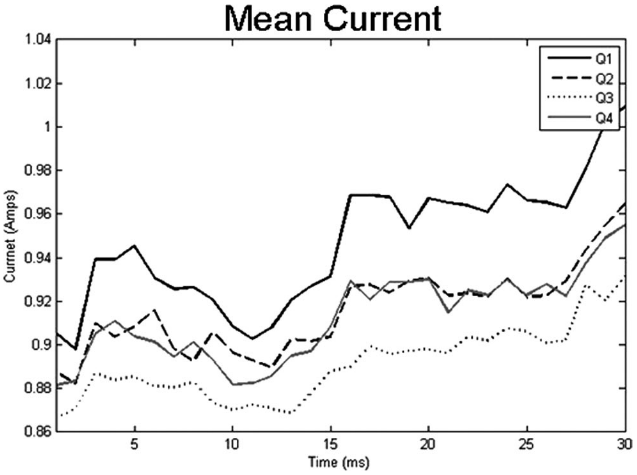

Figure 3. Mean current for each group of waveforms. There was a statistically significant increase of the mean current in the prefailure group.

Discussion

Slaughter *et al.*[8] demonstrated that it was possible to identify acoustically that when the main bearing of the XVE begins to fail. To date, acoustical waveform analysis has been the most accurate method of identifying main bearing wear; however, the predictive capabilities of this method have not been evident. Slaughter *et al.* found no direct correlation between when the main bearing begins to fail and when the main bearing truly fails.

Shao and Nezu used ANNs to predict bearing life in a controlled experimental setup and were able to accurately predict failure and bearing health. The Shao and Nezu[9] neural network was a feed-forward network. Similarly, our ANN has been able to accurately predict 93% of the time whether a pump will fail within 30 days, with an area under the ROC curve of 0.971. We believe that there is potential to predict pump failure at >95% accuracy by adding more pumps into the analysis. Our method is more applicable and accurate than other methods currently being used.

XVE electrical current waveform analysis is a novel noninvasive method to help predict XVE pump failure. A high electrical current, large magnitude signals in the 60–80 Hz range, and high variance of Eigen projection coefficient are indicators that the pump is within the last 30 days of its life.

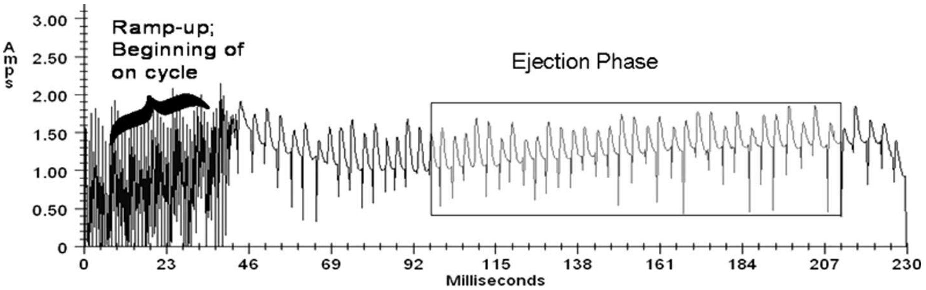

Figure 2. Example of HeartMate XVE electrical current waveform. One cycle of the pump typically lasts 150–250 msec. The ejection phase of the signal contained the highest information content.

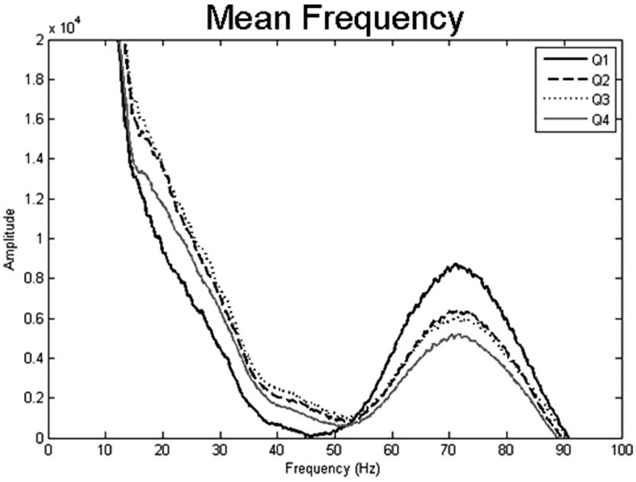

Figure 4. Mean frequency for each group of waveforms. There was a statistically significant deference between the groups. The prefailure group had a higher magnitude in this range.

The results described in this study demonstrate that pump failure detection and prediction is possible. Failure can be predicted by advanced methods of signal processing and with ANNs. Characterization of signal properties specific to a failing HeartMate XVE was essential to this process.

We identified the center portions of the current waveform as having the most valuable information content, because it directly relates to the ejection phase of the pump cycle. During the ejection phase, the motor from which the electrical current waveform originates is under the maximum amount of stress. As the pump nears the end of its life and the main bearing wears down, the cam begins to rub on the pump housing. As the cam begins to rub on the pump housing, the motor must generate more force to compensate. The increased force necessary translates into higher current draws. The higher current draws correlate well with earlier pump failure.

Principal component analysis can aid in characterizing signals by identifying the principle features of the signal. The first Eigenvector of the HeartMate XVE waveform primarily contains information regarding the general waveform. The first Eigenvector is the primary basis of signal. We projected the first Eigenvector onto a known signal, which results in a coefficient. The coefficient directly relates to how similar the known waveform is to the first Eigenvector. Our results show that the Eigenvector projection coefficients are useful predictors of pump failure. This leads us to believe that there is something fundamentally different between the waveform of a failing pump and that of a normal pump.

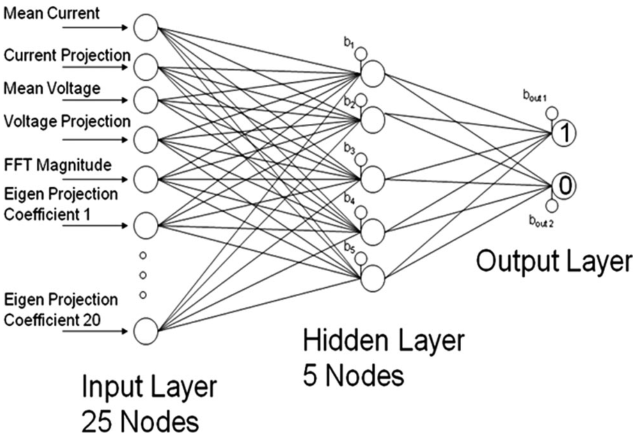

Figure 5. Artificial neural network architecture, consisting of 26 input nodes, 5 hidden nodes, and 2 nodes in the output layer. A returned value of one in the output layer represents that pump failure is predicted.

Table 2. Predicted by Neural Network

	Observed Waveforms (d)	Predicted as Not Failing	Predicted as Failing	Percent Correct (%)
Training	>30	232	6	97
Data	<30	14	64	82
Overall percent				93
Testing	>30	103	5	95
Data	<30	5	26	86
Overall percent				93

As a result of the varying rates that the XVE may run at, time alignment of the waveforms proved to be nearly impossible. Transformation of the waveforms into the frequency domain by use of a FFT solved this problem. The magnitude of frequencies in the 60–80 Hz range was significantly higher when compared with the other groups. The significance of the 60–80 Hz region is unknown. We hypothesize that the magnitude is larger because of the nature of the XVE motor. The XVE motor is a stepper motor with 24 phases. As the pump fails, each phase requires larger amounts of current. As the amount of current needed by each phase increases, the corresponding frequency energy also increases.

By understanding first the characteristics of failing XVE waveforms, it was possible to generate a noninvasive technique to predict pump failure within 30 days. The use of XVE waveforms to predict pump failure is novel and inexpensive. Predicting XVE failure will help clinicians to better assess when the time is appropriate to talk to patients about end-of-life or pump concerns. Close monitoring of these early indicators of pump failure may allow for more timely preemptive LVAD replacement, which directly relates to improved outcomes, particularly now when many Heartmate XVE patients are nearing the end of the expected life time of their pump.[10,11]

Acknowledgment

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