MULTIVARIATE ANALYSIS (MVA) FOR QUALITY DETECTION IN INJECTION MOLDING SYSTEMS IN THE MEDICAL DEVICE COMMUNITY

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Abstract

We describe a new method of point-of-origin quality detection for injection molding systems. The method encompasses data acquisition, Multivariate modeling, reject control and data reporting, provides in-line quality detection of injection molded parts, and real-time reports on fault contributors. We discuss real-world production applications in which MVA is applied using real-time molding parameters to predict quality, with a goal of Parametric Release.

Introduction

The current quality control techniques for injection molding that are in place within the Medical Device Community (i.e. AQL-based lot sample inspection, Statistical Process Control (SPC), etc) do not adequately prevent defective parts from continuing on through the manufacturing process. SPC methodologies for example, typically monitor control charts for 3σ excursions as a measure of out-of-control processes. Invariably, waiting for the detection of a 3σ excursion results in a loss of product. Univariate analysis-based fault detection methodologies are also plagued with high false alarm rates. Additionally, univariate SPC techniques do not take into account parameter interactions and correlations.

The impact of the failure of conventional QC methods for real-time defect capture and rejection is significant in terms of downstream production time, cost and recovery, as well as regulatory impact. The overall cost to production is magnified many times relative to the cost of defect capture at or near the point of origin for injection molding systems. There exist Statistical Process Control (SPC) systems for injection molding tools that contain the option to integrate mold cavity sensors and such can help to reduce the numbers of defective units released to downstream processing and these provide documented benefits. These systems do not, however, explain the source of the process variation, and only give an indication of what is actually occurring in the mold cavity. In order to obtain true parametric release, the source of the variation must be understood and controlled. The addition of Multivariate Analysis (MVA) processing to these solutions is needed to realize the greatest processing advantages and true Parametric Release in parts and processes. MVA analysis of an injection molding process can provide critical improvements in injection molding processing including:

a) More accurate and precise fault detection than can be achieved using conventional SPC
b) The ability to clearly monitor all variables simultaneously
c) Clear views of process drift
d) Real-time identification of those variables most strongly contributing to a fault
e) Real-time, in-line rejection capability
f) Fewer false rejects than are observed when using SPC alone
g) Increased productivity in terms of troubleshooting and problem diagnosis

MVA technology [1-3] is the science of separating the signal from the noise in data with many variables and presenting this data in a simple graphical format. A key advantage of this technology is the ability to take large, unwieldy data sets and reduce them to simple model representations that can be readily understood and employed for quality control purposes. In MVA technology real-time process data is used to create a "current" process model which is numerically contrasted with a previously established "known good" process model. The results of this numerical comparison are two relatively simple decision statistics, DModX and Hotelling's T^2; and these define the nature and extent of observed deviations in the current process from the established "good" process model. The greater the numeric value of Hotelling's T^2, the more likely it is that the current data deviates significantly from the model and that the product is "out of spec". The larger the value of DModX, the greater the likelihood that the current data is influenced by factors or in patterns not present when the original model was formulated.

In this report, we describe the incorporation of MVA methodologies into Quality Control for Fault Detection Analysis (FDC) in the injection molding of medical device components. We describe the use of this methodology for the achievement of improved process understanding, for real-time identification and rejection of

defective parts and for assistance in the identification of corrective action determinations.

System Description

This study employed an MKS Senselink™ QM module for data acquisition and MVA computing. The module is equipped with a web browser interface and has on-board data storage and result outputs. The unit was mounted in the control cabinet of an injection molding press (Figure 1). During the manufacturing process cycle, this module continuously records key process variables including, but not limited to:

Analog Inputs:

a) Temperatures – nozzle and zones
b) Pressures – fill and pack

Digital Inputs:

c) Timing events – mold, fill and pack
d) Shot Position

Optional Inputs:

e) Cavity pressure and mold sensors
f) Area Sensors – i.e. ambient temperature, humidity
g) Ancillary devices – water temperature and dryer

Raw data and MVA/FDC results were stored locally on the module and accessed using the web-based user interface. The results are also available as controller feedback, signals for product accept/reject, and can be sent to network data vaults.

Model Building Procedure

Data collection commenced following installation of the module, connection of the signals from the sensors monitoring the key process variables and user-based variable selection. The selected data was collected over the entire molding process (mold open to mold open). Initially, 9 – 17 trials that were based on a Scientific Injection Molding approach [4,5] were performed to ensure a robust, flexible model. According to Bozelli [6] in Scientific Injection Molding: "*Molding strategies are based on the four key processing variables each scientifically established:*

1. *Plastic Temperature*
2. *Plastic Flow Rate*
3. *Plastic Pressure*
4. *Cooling Rate and Time*

Design of Experiments (DoE) was used to define relative variable contributions and correlations, and a PCA model was built from the DoE data. In this manner, the pattern of the normal operating conditions was defined. Once the initial model was built, each injection molding cycle can be compared with the reference process model. The results of this comparison are the DModX and Hotelling's T^2 statistics. For this study, baseline data from 1000 cycles within the 9-17 run matrix was collected and used to define DModX and T^2 alarm levels for part accept/reject logic.

Case Studies

In order to test the effectiveness of the MVA system for FDC in injection molding, intentional faults were created on a molding tool. The data were then analyzed offline in order to correlate alarms with the actual process contributors to each fault. Figure 2 shows the DModX response of the MVA system to this process and to the induced faults. The plot displays one DModX value calculated per injection molding cycle and is thus a time-series of the DModX statistic for the process. The baseline data showed that an appropriate alarm level in this case is a DModX value of 1.509.

The characteristic and timing of the induced faults to the molding cycle was:

- 13:15 PM: Slight short shot
- 13:30 PM: Large short shot
- 13:41 PM: Slight amount of flashing
- 13:54 PM: Large amount of flashing
- 14:06 PM: Simulated double shot by closing on part.

Figure 2 displays the DModX plot for the injection molding process over the span of time that includes the period in which the faults were introduced. This statistic clearly responds dramatically as each process error is induced; and it is apparent that different kinds of faults give rise to different magnitude and form in the DModX response.

A key characteristic of the MVA system is its ability to "drill down" through the data and identify fault contributors once the fault has been recognized. Figure 2 shows the onset of each particular fault type to correlate with a particular cycle (recall that in the DModX plot, the points on the X-axis each correspond to one cycle in the injection molding process). Each point along this axis has an associated contribution plot containing values for each of the key variables in the process. Figure 3 shows the contribution plot associated with the cycle in which short shots were intentionally introduced into the process. The plot in Figure 3 shows that, of the variables monitored in this process, two showed significant deviation from the normally accepted model values. The injection pack pressure is seen to be significantly below its expected value during the short shot excursion while the shot cushion shows a small but significant positive deviation from its expected value. Figure 4 shows the contribution plot associated with the cycle in which flashing was introduced to the process. Again, injection pack pressure and shot cushion are seen to be the primary deviations from the reference model, but in this case the former shows positive deviation from the expected value while the latter is negative. Figure 5 shows the contribution plot associated with the cycle in which the simulated double shot occurred. In this plot a different pattern of deviations from expected values is observed than for either short shots or flashing.

The DModX approach thus shows not only alarms, but also provides information on the kind of alarm. The combined use of the DModX plot with the Contribution Plots DModX provides information on the correlation structure breaks in the alarm. The breakdown in the pattern of variables is readily apparent in the correlation plots and the pattern of the breakdown is indicative of the characteristics of the fault that has occurred in the process. This identification of fault characteristics is a key concept of multivariate analysis. The methodology monitors not only the value of a variable but also how it relates to other variables in the process.

When the correlation structure / relationship breaks down, MVA detects the break. Such relational breaks are not detected using univariate analysis (UVA), since UVA assumes that all variables are independent. This assumption is not valid in systems where process variables are correlated (most systems).

Results

The use of MVA analysis provides a key advantage in process control. With MVA in place, it is possible to automatically identify defects such as short shots, double shots and excess flash. Once these defects have been identified by the system, it is feasible to automatically divert suspect product and avoid further product loss through downstream product defects that are directly correlated with the original defect. This improves productivity, reduces potential financial penalties and decreases the need for inspection resources.

This study shows that it is possible to identify those process parameters that contribute to suspect product and to reduce problem identification and correction time/prevention time through the use of MVA methods in the injection molding of medical parts. Stability and control of this process has been significantly improved through the increase in process knowledge, resulting in increases in Cp and Cpk values of, typically, 9%. In the long term, it should be possible to build libraries of defect classifications to assist with a broad range of issue classifications and resolutions.

References

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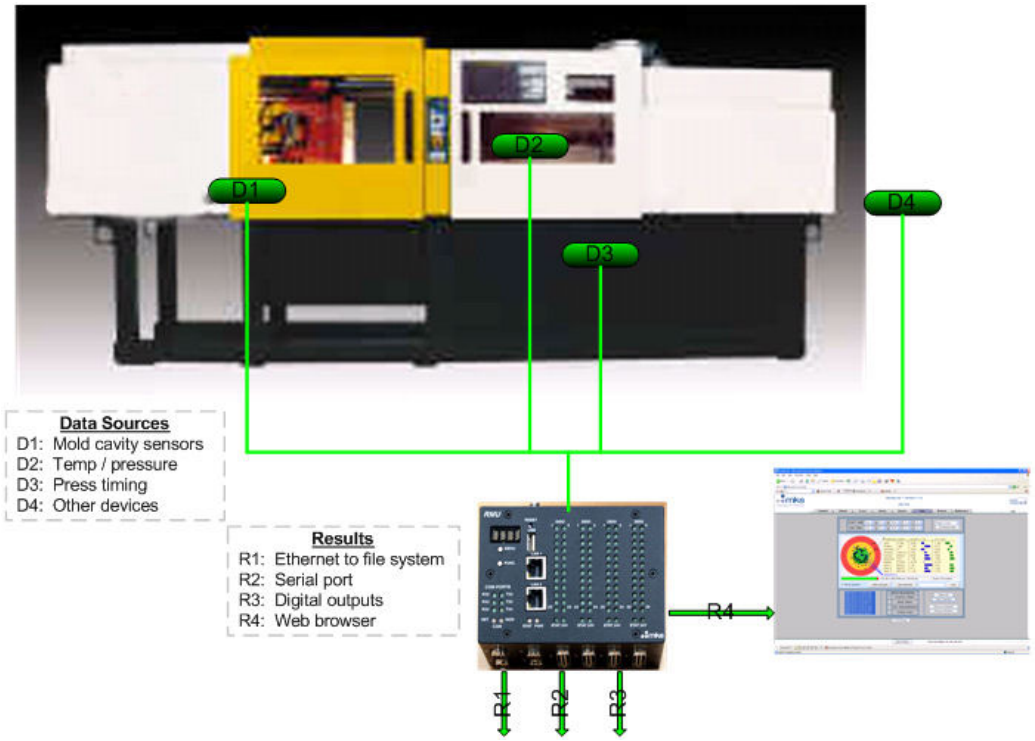

Figure 1.
The data collection and analysis configuration employed in this study.

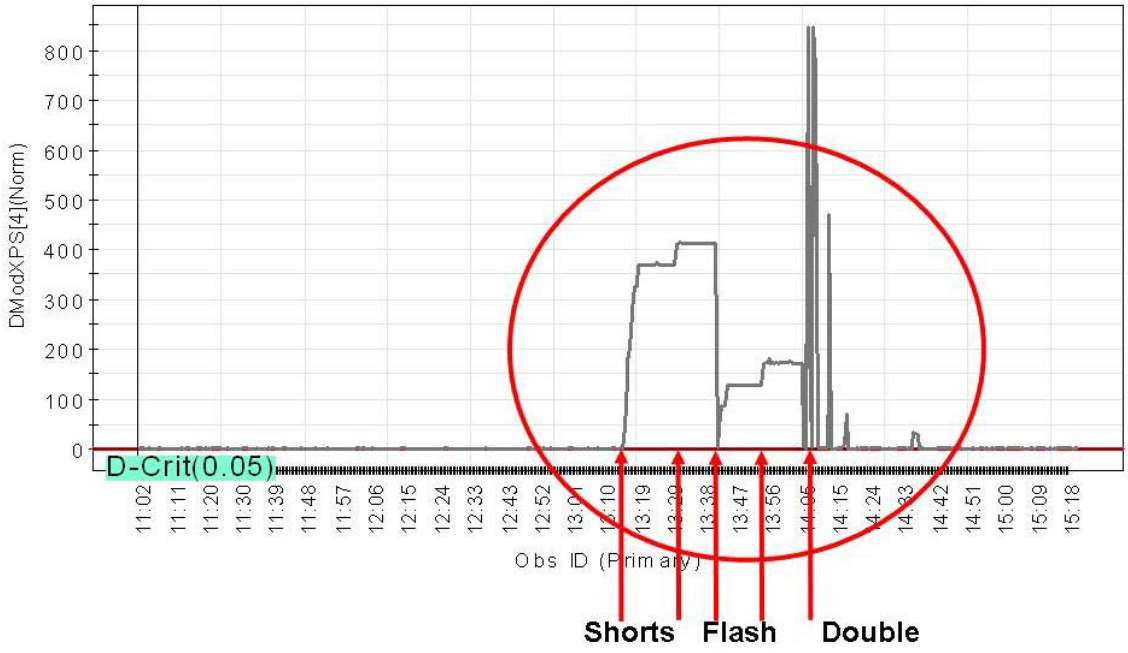

Figure 2.
DModX plot for injection molding process showing the onset of errors in the process and the associated alarm levels in the DModX statistic.

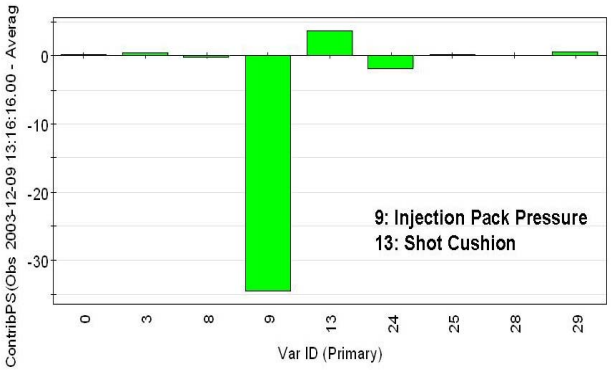

Figure 3.
Contribution plot for the onset of short shots.

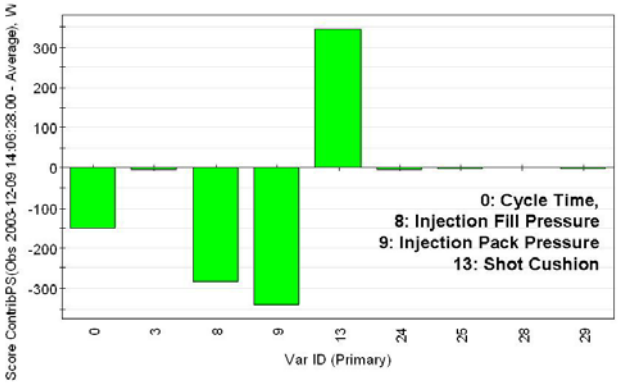

Figure 5.
Contribution plot for the simulated double shot.

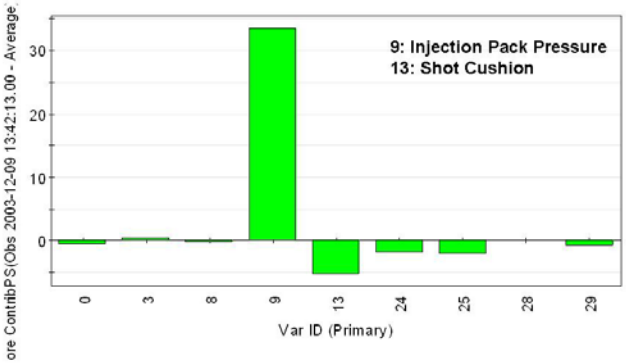

Figure 4.
Contribution plot for the onset of flashing