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Reducing Uncertainty in PHM by Accounting for Human Factors – A Case Study in the Biopharmaceutical Industry

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Abstract

The ultimate goal of prognostics within Through-life Engineering Services (TES) is to accurately predict the remaining useful life (RUL) of components. Prognostic frameworks inherently presume that there is predictability in the failure rate of the system, i.e. a system experiencing exclusively stochastic failure events cannot, by definition, be predictable. Prediction model uncertainties must be bound in some logical way. Therefore, to achieve an accurate prognostic model, uncertainty must first be reduced through the identification and elimination of the root causes of random failure events. This research investigates human error in maintenance activities as a major cause of random failure events, using a case study from the biopharmaceutical industry. Elastomer failures remain the number one contamination risk in this industry and data shows unexplained variability in the lifetime of real components when compared to accelerated lifetime testing in the lab environment. Technician error during installation and maintenance activities of elastomers is one possible cause for this and this research explores how these errors can be eliminated, reduced, or accounted for within the reliability modeling process. The initial approach followed was to improve technician training in order to reduce errors and thereby reduce the variability of random failure events. Subsequent data has shown an improvement in key metrics with failures now more closely matching data from lab testing. However, there is scope for further improvements and future research will explore the role of performance influencing factors in the maintenance task to identify additional causes of variation. These factors may then be incorporated as a process variable in a prognostics and health management (PHM) model developed for the system. The paper will present these data fusion approaches accounting for human factors as a roadmap to improving PHM model reliability.

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Keywords: Prognostics and Health Management (PHM); Human factors; Data Fusion

1. Introduction

Until recently, the concept of condition based maintenance (CBM) has been primarily fault diagnosis, which involves fault detection, identification, and isolation [1]. A major shift in the CBM philosophy was observed with the introduction of expert systems within the CBM framework. This significantly improved the state of the art over previous systems [1]. However, most of these systems use only quantitative information available from sensors to automate the diagnosis task, while qualitative information is rarely exploited [2 – 4]. In contrast, some systems only consider qualitative information and ignore sensor measurements [5], [6]. Little evidence can be found in the literature where both quantitative and qualitative information is concurrently utilised. The difficulty in building a common platform to process both quantitative and qualitative data has hindered the use of such a hybrid system. The integration of these information sources would lead to improved system availability and reliability by increasing interaction via information sharing and coordination for timely preventive maintenance [1]. This work aims to incorporate quantitative probabilistic approaches from the prognostics and health management (PHM) domain with qualitative human factors approaches in order to optimise a predictive framework for the failure probabilities of components used in the biopharmaceutical industry.

1.1. Prognostic Health Management

PHM represents a paradigm shift from legacy condition based maintenance (CBM) frameworks by expanding the

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potentials to accurately and robustly detect and diagnose incipient system faults. The ultimate goal of PHM is reliably predicting system failure times to allow for efficient maintenance scheduling [7]. Recent developments in PHM are encouraging high risk industries in particular, such as the military, nuclear, petrochemical, automotive, pharmaceutical, and aerospace, to adopt PHM systems for increasing system availability, minimizing unscheduled shutdowns, reducing maintenance costs, and increasing safety [8]. In these high risk industries detecting and isolating faults and subsequently predicting the remaining useful life (RUL) of critical components is a crucial task.

A typical PHM scheme consists of three main facets, Fault Detection (D), Fault Diagnosis (FD), and Fault Prediction (FP). Fault detection normally includes fault isolation, which is a task to locate the specific component that is faulty. Fault detection in a broader sense indicates whether something is going wrong in the monitored system, and fault diagnosis determines the nature of the fault after it has been detected. Prognostics deals with fault prediction, and is a task to determine whether a fault is impending and estimate how soon and how likely that fault is to occur. Diagnostics therefore can be defined as posterior event analysis and prognostics as prior event analysis. Prognostics is considerably more efficient than diagnostics in achieving zero-downtime performance. Diagnostics, however, is required when fault prediction of prognostics fails and a fault occurs, and is important from a root cause analysis (RCA) perspective to avoid future failures of a similar nature [9].

1.1.1. Fault Prognosis

Upon fault detection and diagnosis, prognostics becomes a fundamental task of a PHM system which aims to reliably and accurately forecast the RUL of the equipment/system [7] so that it may function for as long as its design intended [10]. RUL is typically a time, cycle, or some other specific context driven expression. The RUL is the prediction of a component or systems functional/operational usage expectancy based on measured, detected, modelled, and/or predicted health state. The RUL is dependent on the intended set of operating conditions or mission to be performed [7].

1.1.2. Uncertainty in PHM

The importance of uncertainty quantification in the PHM context should not be understated. Monitoring the health state of systems, subsystems, and components, the classification of the different types of faults that may occur in these components, and estimating the RUL is critical to support decision makers in assessing whether maintenance intervention is necessary or not. Without quantifying the associated uncertainties, remaining life projections have little practical value within PHM systems [11]. It is the comprehension of the corresponding uncertainties that enables the development of a business case that addresses prognostic requirements. The assumption of data monitoring without uncertainty is particularly problematic, as this forces maintenance planning to become an exercise in decision making under uncertainty with sparse data [12]. In practice, the possible sources of uncertainty that may arise in a PHM system are:

- Uncertainty in the signal measurements
- Uncertainty in the models adopted at each data management stage
- Selected model parameters
- Uncertainty due to the inherent stochasticity of the physical processes
- Variability in human decisions relating to the PHM system output

Essentially, the inherent uncertainties which propagate through PHM systems mean that the PHM output can never be perfectly reliable [9]. We argue that another source of uncertainty in any PHM model is the uncertainty associated with the human interactions with the system, e.g. maintenance or installation work completed. We argue that the effect of incorrect maintenance or installation has sufficient impact for it to be regarded as a separate source of uncertainty in its own right. Most PHM models assume that the work done by a maintenance technician has been completed to a requisite standard, thereby allowing predictive analytics a consistent operational performance benchmark from which to operate. However, in practice this is often not the case, with a large variability in numerous aspects related to the ability of a maintenance technician to effectively carry out their work. In an attempt to address this issue there have been systematic methods developed to improve the performance of human-machine systems, such as Human Error Probability (HEP) assessments [13]. Incorporating such HEPs in the development of operational procedures can significantly improve the overall reliability of the system [14] and this work explores the benefits of similarly accounting for human variability in the context of PHM.

1.2. Human Performance

Natural variation in human performance, occasionally resulting in errors, is a potential source of uncertainty in predicting remaining useful life of components. Human error is defined by Reason [15] as '*a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some chance agency*'. The variation giving rise to errors may be influenced by the conditions in which tasks are undertaken, such as environmental conditions, quality of procedures, level of training provided, etc. Human error is an important consideration in the process industry, as it is well established that a significant proportion of human errors occur during maintenance activities [13]. Human error is cited as a major cause of pharmaceutical manufacturing failures, with human error being attributed to approximately 50% of recorded incidents [16], a significant proportion of these occur during maintenance activities [13], costing the industry significant amounts of time and money.

Human Factors, the discipline that aims to optimize human well-being and overall system performance [17] provides some possible approaches to accounting for these variations thereby improving the accuracy of the prediction. Foremost among the relevant Human Factors approaches, in addition to HEP, is Human Reliability Analysis (HRA) [18], which aims to identify and quantify possible human errors in a system. HRA tools, such as THERP [19], HEART [20], SPAR-H [21], and TRACER [22] start by identifying possible human errors within a task or system and subsequently use databases to assign an expected error rate. This error rate can be modified by performance shaping factors (PSFs), or error producing conditions, which increase the probability of an error during a task. Performance shaping factors include factors external to the individual such as the environment in which the task is conducted, the work hours, the organisational structure, job and task instructions, equipment characteristics, and task characteristics. More individually, psychological (e.g. time pressure, distractions, etc.) and physiological (e.g. fatigue, hunger, radiation etc.) stressors can also influence task performance and error rates. The base error rate for a particular task, such as valve installation, will remain constant for that task regardless of the individual valve. However, the PSFs vary according to the specifics relating to each individual valve and may influence the likelihood of correct maintenance actions.

2. Approach

A case study in the biopharmaceutical industry was followed in order to study the reduction of uncertainty and the role of human interactions in component reliability. This applied research centres around the RUL prediction of elastomeric soft parts, and subsequently optimising a decision support system for the timely maintenance of these parts. The aim is to accurately predict both the progressive degradation of the elastomers and their sudden failure via cracking in situ. The relationship between these two failure modes has been defined within a Markov Chain framework, as shown in Figure 1. T is defined as time between degradation states.

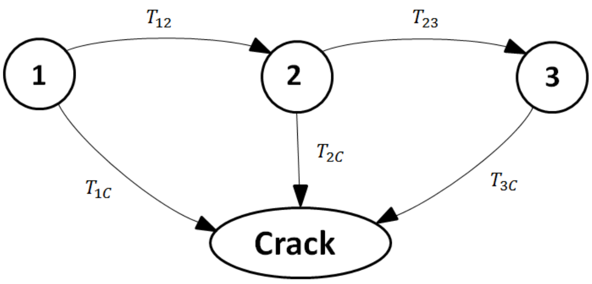

Figure 1: Markov Chain structure of the components two failure modes

The elastomer in question, ethylene propylene diene monomer (EPDM), is a rubber widely used as the sealing element in flow control valves in the biopharmaceutical and petrochemical sectors. In its valve application use in biopharmaceuticals, EDPM is a product contact material, used partly to maintain the integrity of the hermetically sealed environments within production bioreactors. As such there is a significant risk associated with the sudden failure of the rubber in situ, from both a safety and commercial perspective. There is currently no known way to monitor the health state of the elastomer in situ, therefore robust predictions must be established in order to set the maintenance windows at an appropriate frequency. Elastomer failures pose a major risk in the biopharmaceutical industry as a whole. Next to calibrations, valve diaphragm maintenance is the most cost intensive part of maintenance in biopharmaceutical operations. A survey of BioPhorum member companies in 2012 demonstrated that for a typical biotech plant, soft parts [23]:

- maintenance programs account for over 50% of all planned maintenance activities
- drive 20% of all equipment related deviations
- account for approximately 10% of all corrective maintenance actions
- present the number one contamination risk

There are two identified failure modes of the EPDM components identified in this work. The first failure mode, and the most common, is the gradual degradation of the EPDM as it is subjected to numerous harsh environmental conditions, such as high temperature saturated steam, cleaning agents and chemical detergents, sparge gases, multiple product mediums, and final purified product. The progressive degradation of the material has been defined qualitatively within three states; state 1 degradation is characterised by mild discolouration, melting, and weir markings, state 2 degradation shows signs of more severe melting, material flow, and surface creasing, while state 3 is characterised as severe degradation such that significant melting, material flow, and material creasing is evident. The second failure mode, the focus of this work, is the sudden cracking of the diaphragm regardless of its degradation state. These categories are shown in Figure 2.

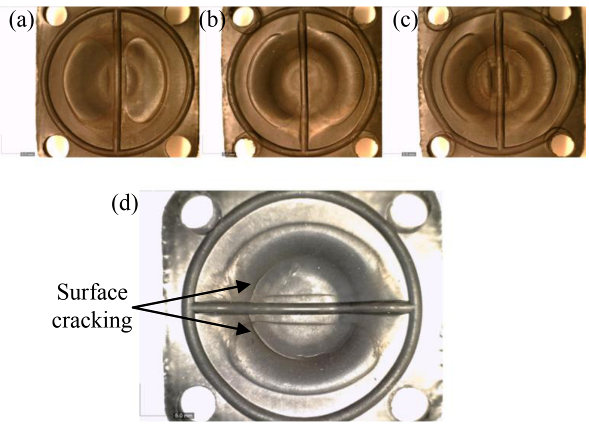

Figure 2: (a) State 1 material degradation, (b) State 2 material degradation, (c) State 3 material degradation, (d) Surface cracking of EPDM

2.1. Role of Competence

The organisation involved in this research has previously identified technician competence as a key area for improvement in order to improve elastomer reliability and a new training scheme was introduced in an attempt to reduce errors and thereby reduce the variability of random failure events. In order to bridge the gap between laboratory accelerated lifetime testing results and those encountered in service, and to address specific issues seen in the field believed to be responsible for a high infant mortality rates, an optimised maintenance technician training program was designed and implemented. The multiple root causes for leaking valves were identified as elastomer failures from actuator, fastener, and installation issues. The previous training had not been revised for several years prior. The revised training focused on the following:

- inappropriate tooling and maintenance practices, specifying in detail all components and auxiliary equipment to be used
- revised and detailed flow diagrams of the work to be carried out in a step-wise fashion
- valve and elastomer design issues, previously resulting in valve failures, addressed via the introduction of new designs in conjunction with the valve suppliers
- fastener replacement initiated site-wide

The responsibility of updating training material on a bi-annual basis and communication of any changes made was handed over to technicians ensuring the ownership of the training material. Subsequent data has shown an improvement in key metrics with failures now more closely matching data from laboratory-based testing, specifically:

- a reduction of corrective maintenance actions per batch by ~25%
- a ~35% reduction in investigations related to damaged diaphragms and leaking valves
- a ~270% increase in the number of successful batches with no quality investigations needed
- the maintenance of a 95% batch success rate even at increased production rates
- a reduced maintenance cost per batch
- a 12% decrease in potential contamination issues

There is however scope for further improvements due to the continued observance of sudden early stage failures of the components in service. This research explored the PSFs that may influence accurate and reliable completion of the installation procedure. The first step in the study was to identify the PSFs that may influence the task. A review of PSFs in one of the main HRA tools, THERP [20], was undertaken and the contextually relevant PSFs were identified. These were then used to develop a semi-structured interview format. The interviews were designed to identify the factors that increase the difficulty of valve installation, and to develop an installation difficulty metric which could be applied to each component in the study.

It was critical to assess the difficulty of valve installation, as incorrect assembly and tightening of the actuator, diaphragm, and valve body is one of the main reasons for failure and leakage of diaphragm valves [24]. The valve assembly requires four bolts to be tightened to specific values, depending on valve size, in a crisscross pattern over three passes. If one or more bolts are torqued higher than the others, the clamping force will be unevenly distributed over the diaphragm. Critically, this can lead to the uneven forces on the diaphragm leading to premature and unforeseen cracking of the diaphragm [24], most likely due to uneven stress distributions within the EPDM.

Table 1: Sample failure states as retrieved from service

Presence of Crack Degradation State	No	Yes	Total
1	72	6	78
2	19	4	23
3	1	3	4
Total	92	13	105

The breakdown of the samples retrieved from service after industrial usage of between 6 and 24 months in this case study is shown in Table 1. As shown, there are examples of cracking in each of the three degradation states, validating the need to treat the cracking failure mode as a separate special cause deviation.

3. Results

3.1. Review of PSFs

A review of external PSFs in THERP was undertaken to identify those PSFs that may be relevant to the valve installation task. THERP [19] was used as it contains the most comprehensive set of performance shaping factors. The following PSFs were identified:

- Quality of the environment (e.g. temperature, humidity, lighting, noise)
- Work hours / work breaks
- Availability / adequacy of special equipment, tools, supplies
- Frequency and repetitiveness
- Task speed
- Task load
- Distractions
- Fatigue
- Movement constriction
- State of current practice or skill

Some of these PSFs had to be disregarded, as it was not possible in this study to identify individual technicians or collect data on their individual state while installing specific valves. Therefore, work hours, task load, distractions, and fatigue were not further investigated. The remaining PSFs were investigated in more detail in a set of interviews with the technicians responsible for the installation task.

3.2. Technician Interviews

The basic structure of the interview centred on the following questions, however the interview was structured in a semi-formal manner to help elicit a more natural response from the interviewee:

- What makes maintenance process more difficult from a technician's perspective?
- Could any of the valve components become damaged during installation or maintenance?
- In what ways can a valve be installed incorrectly?
- How much does each of the following factors increase the risk of incorrect installation, if at all?
  - Valve complexity
  - Valve size
  - Procedure information for the valve
  - Accessibility of the installation location
  - Lighting in the installation location
  - Noise in the installation location
  - Distractions in the installation location
  - Technician experience level
  - Time available to perform the task
  - Time of day or night

The main conclusions reached from the interview was that the enhanced training programs have largely eliminated many of the human factors issued previously encountered, such as procedural information errors, incorrect installation practices, and time pressure issues. The interviews with the technicians revealed two key PSF's acting as limiting factors in the successful installation and maintenance of the valves. These were the accessibility of the valve location, and the size of the valves. The accessibility was important as this affected the technician's ability to manoeuvre either their bodies or the tooling into the correct position. For example, if the valve is located at height, or behind a bank of pipe work, or in a tight crawl space, the ability of the technicians to apply the correct torque values to the valve bolts is diminished. Similarly, the size of the valves, with diaphragms ranging from 25mm to 100mm, has the effect of making it more difficult to install if the valve is smaller, due to smaller parts which are more difficult to handle. The technicians felt however that the valve size would have only a minor impact in comparison to valve accessibility.

4. Discussion

Valve size and accessibility will both be included as covariates in a Cox Proportional Hazards modelling approach [25] in order to predict the two failure modes. As shown in Figure 1, the probability of having a crack in a diaphragm is contingent upon the current diaphragm state. Along with the diaphragm degradation state the size of the valve and an Accessibility Difficulty Metric (ADM) will be included in order to improve the prediction of cracking.

4.1. Accessibility Difficulty Metric (ADM)

Similar to the work of Baraldi et al [26] and Zio et al [27] a visual interface has been developed for maintenance technicians to assess the PSF's characterising the context in which the maintenance and installation tasks are performed. The interface is intuitive and guarantees assessment repeatability across all systems. The proposed interface is based on the use of anchor points that represent particular conditions, which are well defined. The allocation of the anchor points on a numerical scale will be performed by interviewing maintenance technicians with considerable experience in valve installation and appropriately aggregating their conclusions. The sub PSF's defining the anchor points of the ADM, defined in conjunction with technicians, are:

- No Accessibility Difficulty: valve at an appropriate height, facing towards the technician, with no discernible obstructions in the area
- Mild Accessibility Difficulty: valve at height. Installation or maintenance tasks require auxiliary equipment to reach valve location. Otherwise no obstruction
- Moderate Accessibility Difficulty: valve obstructed by other equipment, such as pipe work, pumps, motors etc., or valve in physically difficult to reach location, such as in a crawl space
- Severe Accessibility Difficulty: combination of two or more of any mild or moderate valve obstruction conditions

The scale will be based from 0 to 100. 0 will act as the 1st anchor point, 'No Accessibility Difficulty', with 100 acting as the 4th Anchor point, 'Severe Accessibility Difficulty'. The 2nd and 3rd anchor points lie in intermediate points along the scale. The scale is shown in Figure 3.

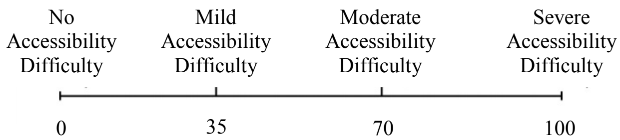

Figure 3: Accessibility Difficulty Metric scale

Each system and valve in the case study will be assessed separately, and the results will then be aggregated onto a common scale. These common scales will then be further aggregated from multiple technicians to come up with the final score for each valve. Statistical relationships can then be determined based on the valve ADM and the presence of cracking in service. This relationship will become more robust with continued data collection from industrially used parts. The ADM can then be incorporated into probabilistic assessments of premature diaphragm cracking. This represents a novel data fusion approach whereby qualitative assessments are combined with quantitative usage history data in order to predict component RUL and the likelihood of infant mortality due to surface cracking.

5. Conclusions

To date this research has postulated the potential importance of the role of human factors in improving predictions of remaining useful life, and has collected qualitative evidence from experienced maintenance technicians on the performance shaping factors influencing the installation of elastomeric soft parts in the biopharmaceutical industry. Accounting for these conditions should reduce one source of uncertainty from the PHM model, and improve overall prediction of RUL for these components. The next phase of the research will collect quantitative data on the two factors identified in this study, accessibility and valve size, and combine this with quantitative data on usage history to test the accuracy of the model.

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