Zero defect manufacturing: a self-adaptive defect prediction model based on assembly complexity

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Abstract

The prediction of defects occurring during manufacturing processes is one of the strategies to be implemented by organizations to reach the goals of Zero-Defect Manufacturing (ZDM). In low-volume productions, characterized by a high level of complexity and customization, defects prediction may be challenging owing to the small amount of historical data typically available. This paper proposes a diagnostic tool that provides an in-line identification of critical steps of assembly processes. The method is based on a self-adaptive defect prediction model of the process, updated as new data are acquired. Assembly complexity of both the process and the design are used as predictors of the defect model. The methodology identifies critical assembly workstations where the respective average defectiveness deviates from the average defectiveness predicted by the model. Detecting critical workstations facilitates quality engineers in identifying the causes of non-conformities and undertaking appropriate corrective actions. The relevance of the method is emphasized by an application to a real case study related to the assembly of rotating ring wrapping machines used in end-of-line packaging.

Keywords: zero-defect manufacturing, defect prediction model, assembly process; assembly complexity; low-volume production.

1 Introduction

Customer needs require products with a high degree of customization, with an increasingly high level of quality. This inevitably requires manufacturing companies to continuously adapt to the changes imposed by customers: short product life cycles, high customization, high quality and low costs.

Therefore, in order to remain competitive, companies started new strategies to achieve higher product quality while keeping costs as low as possible (Psarommatis and Kiritsis 2019). Among these, an emerging one is the so-called Zero-Defect Manufacturing (ZDM), which aims to decrease and mitigate failures and defects in different manufacturing processes. The main challenges associated with ZDM are the integration of large amounts of data from many sources, the development of advanced technologies and methods, modeling of ZDM, and timely real-time computation (Lindström et al. 2020; Psarommatis et al. 2020; Eger et al. 2018). However, achieving these goals is not straightforward (Ferretti et al. 2013). Strategies to achieve ZDM goals include the Detect, Prevent, Predict and Repair of a defect (Psarommatis and Kiritsis 2018; Psarommatis et al. 2020). Amongst all, the most critical strategy is defect detection because the others rely on data collected in the detection phase (Psarommatis and Kiritsis 2019).

The detection of defects is a very important step of a manufacturing process (Iglesias, Martínez, and Taboada 2018; Galetto, Verna, and Genta 2020; Galetto et al. 2020, 2018; Liong et al. 2020). Indeed, defects generated during production can drastically affect the product, both in quality and cost terms (Genta, Galetto, and Franceschini 2018). To cope with the in-process detection of defects, appropriate process control and monitoring systems and adequate predictive maintenance techniques should be adopted by manufacturing companies (Aivaliotis et al. 2019; Zhou et al. 2019; Papavasileiou et al. 2021; Aivaliotis et al. 2021; Papacharalampopoulos, Petrides, and Stavropoulos 2019; Anyfantis, Stavropoulos, and Chryssolouris 2018; Papacharalampopoulos et al. 2020). Although such approaches are straightforwardly applied to understand, monitor, and improve performances of mass production processes, their adoption is not devoid of issues in the case of low-volume productions.

Low-volume productions are typically made up of highly customized and complex products, tailor-made for customers. For this reason, collecting enough data in the short term to apply the above traditional techniques is trivial (Del Castillo et al. 1996; Trovato et al. 2010; Marques et al. 2015; Does 1997). Therefore, it is necessary to identify new approaches to diagnose the production process and then improve it. Over the past few decades, some statistical process control methods specific to low-volume production have been proposed in the literature, highlighting advantages and shortcomings (Verna et al. 2020b; Celano et al. 2011).

This paper aims to propose a novel and practical diagnostic tool suitable for the assembly of low-volume productions. The overall assembly process is decomposed into workstations, which are process steps in which a specific assembly operation is performed. The proposed tool, in line with ZDM goals, aims at detecting assembly workstations that are critical in terms of defectiveness. The tool is built upon a self-adaptive defect prediction model, which can be updated as new data becomes available. The predictors of the model are the complexity factors of both the process and the design. Two specific Research Questions (RQs) are addressed in the manuscript:

RQ1: *How can the defect prediction model be exploited as a diagnostic tool to detect critical workstations?*

RQ2: *How do model parameters self-adapt over time as new data are acquired from individual workstations?*

This study aims to contribute to the growing area of research about zero defect manufacturing by extending previous research conducted in the field. A novel practical diagnostic tool to in-line detect defective workstations relying on a self-adaptive prediction model is proposed. This approach represents a novelty compared to previous models (e.g. Shibata (2002) and Su et al. (2010)) mainly for its self-adaptability, diagnostic accuracy and timeliness.

The remainder of the paper is organized as follows. In Section 2, a review of methods for assembly defect detection and prediction is proposed. Section 3 presents the self-adaptive defect prediction model for low-volume productions. Section 4 illustrates the diagnostic tool to identify critical workstations and improve assembly process. The relevance of the approach is highlighted by its application to a case study in the field of wrapping machine assembly. Finally, Section 5 summarizes the original contributions of the research, focusing on its implications, limitations and possible future developments.

2. Overview of methods for assembly defect defection and prediction

In the last years, a considerable body of research has been dealing with the problem of defect generation in manufacturing because of the relevance of the topic from an engineering and economic point of view. The sources of these defects can be highly diverse, depending on the product and the manufacturing context. The importance of quality control and, more specifically defect detection, has particularly taken hold in assembly manufacturing processes, as the product life cycle requires a faster response and a lower defect rate (Zhong, Liu, and Shi 2010). Among the various faults and defects that can occur in assembly, human errors still weigh heavily, especially in low-volume production, where many human interventions and limited automation exist during the production process. For instance, 25% of the total assembly errors are induced by human mistakes in semiconductor assembly (Shibata 2002) and operator errors account for 20% of the total defects in copier assembly (Su, Liu, and Whitney 2010). To cope with these high percentages, defect detection and prediction methods have been developed in the scientific literature. For instance, Caputo et al. (2017) developed a quantitative model to assess error probability and the error correction costs in part feeding systems for assembly lines to compare alternative part feeding policies and identify corrective measures. Another line of research focused on the close relationship between assembly complexity and human mistakes to predict defects (Hinckley 1994; Shibata 2002; Su, Liu, and Whitney 2010; Antani 2014; Krugh et al. 2016a; Falck et al. 2017b; Galetto, Verna, and Genta 2020; Le, Qiang, and Liangfa 2012; Verna et al. 2021). Indeed, if assembly complexity is not managed adequately at the early stages of process planning, it can increase assembly time and errors and reduce assembly quality and efficiency (Alkan 2019; Krugh et al. 2016a; Falck et al. 2017a, 2016). To this aim, several prediction models were developed, mainly for mass productions. In the wake of the prediction model proposed by Hinckley (1994), derived by using long-term defect data from automobile, hard disk drive and semiconductor companies involving tens of millions of parts and assembly operations, Shibata (2002) adapted it to Sony's home audio products assembly. Several thousands of data related to four different models of audio equipment produced over months were analyzed in the study. Later, Su et al. (2010) developed a new defect model to match the characteristics of copier assembly. Antani (2014) used manufacturing complexity, estimated to incorporate variables driven by design, process and human factors, to predict product quality reliably in mixed-model automotive assembly. Such an approach was adapted by Krugh et al. (2016b, 2016a) to automotive electromechanical connections in a large complex system. Falck et al. (2017b) designed a tool to predict and control operator-induced quality errors by developing a method for predictive assessment of manual assembly complexity.

In the modern framework of Industry 4.0, the growing data sets coming from the ongoing digitalization process can be used by Artificial Intelligence and especially Machine Learning (ML) applications to acquire knowledge from historical events. In particular, ML techniques have exhibited great effectiveness in the domain of manufacturing in analyzing complex systems and solving problems (Z. Kang, Catal, and Tekinerdogan 2020), including product quality and fault detection. Several reviews and surveys on data mining and ML applications focusing on the issue of quality in manufacturing have been published in the literature, see, e.g., Weichert et al. (2019), Cadavid et al. (2020), Dalzochio et al. (2020), Fahle et al. (2020), Kang et al. (2020). Typical industrial applications for quality improvement based on ML can be found in fields such as plastic injection molding and semiconductor manufacturing due to the high amount of data points and the short cycle times (Khakifirooz, Chien, and Chen 2018; Chien, Liu, and Chuang 2017).

The major topics addressed by ML in the area of product/process quality improvement are (*i*) root cause analysis, (*ii*) quality prediction: virtual metrology and early prediction, and (*iii*) systems diagnostics. Root cause analysis is the analysis of existing data records to extract relevant features and feature combinations for high or low product quality (Weichert et al. 2019). Virtual detection, also called virtual metrology or quality prediction in the literature, refers to a set of algorithms used to find a defect without measuring the actual part when the physical measurements are not possible or too expensive, as in semiconductor manufacturing (Psarommatis et al. 2020; S. Kang and Kang 2017). Furthermore, some authors moved further, trying to make a reliable prediction of the final quality at the early stages of the process and identify relations between process steps. Hence, correcting actions before finishing the whole production process may be undertaken (Chen and Boning 2017). Diagnostic systems within the production line may monitor both the product itself (part diagnosis) and/or the machines (equipment diagnosis). Both approaches signal a part/machine condition that is abnormal or becoming abnormal, requiring corrective action to be taken (Z. Kang, Catal, and Tekinerdogan 2020). Although the extensive use of ML techniques for manufacturing quality control and improvement, some problems are still not fully addressed. First of all, the lack of relevant data or difficulties in getting access to the machine's control systems may compromise ML performance.

For this reason, ML is primarily applied in highly complex processes, where a huge amount of data is generated from production. Such a problem might be overcome, at least partially, with time passing to gain expertise, fill storages, and break down obstacles by hardware and software. The lack of sufficient data is one of the main obstacles to adopting ML approaches in low-volume production systems. Indeed, the cycle time is relatively long due to the high flexibility and diversity of products and, typically, the many human interventions and limited automation make the adoption of ML methods extremely difficult.

2.1. Defect prediction models for mass productions

In this section, the most reliable models for predicting assembly defects, developed for mass production, are presented.

According to Shibata (2002), a generic product assembly process can be decomposed into a series of process steps, also referred to as workstations, in which a specific task is performed. A certain number of job elements in each workstation, i.e., elementary operations, is carried out (Aft 2000; Shibata 2002). The job elements are the minimum components of a specific task. These have easily identifiable starting and stopping points and are repeatable regularly throughout the workday. To predict the defects per unit occurring in each i-th workstation (DPU_i), a process-based complexity factor for each workstation, $Cf_{P,i}$, was considered as a predictor, defined as follows:

$$Cf_{P,i} = \sum_{j=1}^{N_{a,i}} SST_{ij} - t_0 \cdot N_{a,i} = TAT_i - t_0 \cdot N_{a,i} \quad (i = 1, \ldots, m), \tag{1}$$

where:

- the index i refers to the generic i-th workstation;
- $N_{a,i}$ is the number of job elements in the workstation i;
- SST_{ij} is the Sony Standard Time spent on the job element j in the workstation i;
- TAT_i is the total assembly time related to the workstation i;
- t_0 is the threshold assembly time, i.e., the time required to perform the simplest assembly operation, below which neither assembly operations nor assembly defects should exist (Shibata 2002).

The assembly times SST_{ij} used in the model are derived from the Sony Standard Time (*SST*), a time estimation tool commonly adopted for electronic products. Accordingly, they are the standard times in which the operators should complete each job element and not the actual assembly times. The correlation relationship between $Cf_{P,i}$ and DPU_i derived from experimental data was as follows (Shibata 2002):

$$DPU_i = \frac{(Cf_{P,i})^K}{C}, \tag{2}$$

where C and K are two regression coefficients obtained by the linearization of the function, in the form:

$$logDPU_i = K \cdot logCf_{P,i} - logC. \tag{3}$$

As evidenced by Shibata [(2002)], the time-related measures, and therefore the $Cf_{P,i}$, may not capture all the sources of defects. For this reason, a second predictor was introduced, i.e., the design-based assembly complexity factor $Cf_{D,i}$ (Shibata 2002). It was defined as the ratio between an arbitrary calibration coefficient, K_D, and the Ease Of Assembly (EOA) coefficient of the corresponding workstation, D_i, estimated through the assembly/disassembly cost-effectiveness (DAC) method developed in Sony Corporation (Yamagiwa 1988), as follows:

$$Cf_{D,i} = \frac{K_D}{D_i}. \tag{4}$$

The correlation relationship between $Cf_{D,i}$ and the DPU_i can be expressed as follows:

$$DPU_i = a \cdot Cf_{D,i}^b, \tag{5}$$

where a and b are again regression coefficients obtained by the linearization of the function, in the form:

$$logDPU_i = b \cdot logCf_{D,i} + loga. \tag{6}$$

By combining Eqs. (2) and (5), a bivariate prediction model was derived, which can be written as:

$$DPU_i = k_1 \cdot (Cf_{P,i})^{k_2} \cdot (Cf_{D,i})^{k_3}, \quad (7)$$

where k_1, k_2 and k_3 are regression coefficients that may be obtained by a power-law nonlinear regression or by the linearization of the function in the form:

$$logDPU_i = k_2 \cdot logCf_{P,i} + k_3 \cdot logCf_{D,i} + logk_1. \quad (8)$$

It has to be remarked that, although Eq. (7) is linearizable, as shown in Eq. (8), it is preferable to implement a nonlinear regression model when dealing with few non-repeated data and affected by high variability, as in the case of DPUs, because of the presence of a retransformation bias (Galetto, Verna, and Genta 2020).

In a subsequent investigation, Su et al. (2010) remarked that the model proposed by Shibata might not be directly suitable for other products, such as electromechanical products. Therefore, instead of using *SST*, a new process-based assembly complexity factor was formulated based on Fuji Xerox Standard Time, a more suitable time estimation approach for copier production. In addition, since DAC method was specifically developed for Sony electronic products, see Eq. (3), they proposed a different approach to evaluate the design complexity, based on the technique developed by Ben-Arieh for assessing the degree of difficulty of assembly operations (Ben-Arieh 1994; Su, Liu, and Whitney 2010). First, l parameters - 11 in the specific case of copier assembly – are chosen as criteria for evaluating the design-based assembly complexity. Then, the weights of the l criteria are allocated using the Analytic Hierarchy Process (AHP) approach (Wei, Chien, and Wang 2005; Saaty 1980). In detail, e evaluators - 6 assembly engineers in the study of Su et al. (2010) - are asked to compare the relative importance of each parameter in determining the difficulty of inserting a part into a product. From such evaluations, the weight w_q of the l parameters and the corresponding degrees of difficulty are obtained. The degree of difficulty, denoted as A_{kqi}, i.e., the evaluation of the parameter q in the workstation i estimated by the evaluator k, is rated by scores between 0 and 10. Accordingly, the new design-based complexity factor was redefined as follows (Su, Liu, and Whitney 2010):

$$Cf_{D,i} = \sum_{q=1}^{l} \left(w_q \cdot \frac{1}{e} \cdot \sum_{k=1}^{e} A_{kqi} \right) \quad (i = 1, \ldots, m). \quad (9)$$

The correlation between each re-designed assembly complexity factor and the *DPU* was tested, showing that the best regression function, in both cases, was a cubic polynomial model. In addition, the re-designed process- and design-based complexity factors were also integrated into a new bivariate prediction model, whose behavior was confirmed to be again cubic (Su, Liu, and Whitney 2010). Nevertheless, in a recent study, Galetto et al. (2020) proved that the cubic models resulted from the logarithmic transformation bias occurring when predicting low defect rates, thus confirming the adequacy of the power-law behavior of Eqs. (2), (5) and (7).

3. A novel self-adaptive model to predict defect in low-volume productions

In this section, a self-adaptive defect prediction model designed for low-volume productions is proposed. Such a model combines the approaches proposed by Shibata (2002) and Su et al. (2010) in order to make the model as general as possible and applicable to most assembly processes. In detail, as mentioned in Section 2.1, the product assembly process is decomposed into m workstations in which $N_{a,i}$ elementary operations (job elements) are performed (Shibata 2002). In each i-th workstation, a specific operation is carried out. According to Shibata (2002), it is assumed that errors made by operators in performing a certain elementary operation in a workstation can introduce at most one typology of a defect in the product. Consequently, the total number of possible defects within a certain workstation is at most equal to the total number of elementary operations in the same workstation. In practical applications, this assumption is reasonable when a refined segmentation of elementary operations is performed in each i-th workstation.

Referring to Eq. (1), the process-based complexity factor adopted in the proposed model, instead of Sony standard times, makes use of the standard times in which an operator should complete each job element. These can be obtained by the predetermined motion time system Methods–Time Measurement (MTM) (Maynard, Stegemerten, and Schwab 1948). Thus, Eq. (1) may be rewritten as:

$$Cf_{P,i} = \sum_{j=1}^{N_{a,i}} ST_{ij} - t_0 \cdot N_{a,i} = TAT_i - t_0 \cdot N_{a,i} \quad (i = 1, \ldots, m), \tag{10}$$

where ST_{ij} is the standard time spent on the job element j in the workstation i.

Referring to the design-based complexity factor, the methodology adopted follows Su et al. (2010) approach, described in Section 2.1. Specifically, the l parameters have to be chosen, according to the product to be assembled, from the list of parameters related to the parts' geometry (geometry-based parameters) and to the type of contact between components (non-geometrical parameters), specified by Ben-Arieh (1994) (see Table 1).

Table 1 – Design parameters of assembly operations (Ben-Arieh 1994)**.**

Geometry-based parameters		**Non-geometrical parameters**	
(i)	Alignment of components	(xii)	Belt contact
(ii)	Amount of support required for the assembly operation	(xiii)	Clamp fit
(iii)	Force required	(xiv)	Gear contact
(iv)	Interference (reachability) to the assembled component	(xv)	Position contact
(v)	Length of components intersection	(xvi)	Snap contact
(vi)	Mating component's length	(xvii)	Spring contact
(vii)	Mating direction		
(viii)	Ratio of length to width (diameter) of the mating component		
(iv)	Ratio of the mating component's weight to the mated one		
(x)	Shape		
(xi)	Stability of the resultant assembly		

The weights w_q of the l parameters are allocated using the Analytic Hierarchy Process (AHP) approach (Ben-Arieh 1994; Wei, Chien, and Wang 2005; Saaty 1980), according to Eq. (11):

$$w_q = \frac{\left(\prod_{r=1}^{l} \alpha_{qr}\right)^{\frac{1}{l}}}{\sum_{q=1}^{l}\left(\prod_{r=1}^{l} \alpha_{qr}\right)^{\frac{1}{l}}} \qquad (q = 1, \ldots, l), \tag{11}$$

where:

- α_{qr} is the relative importance of parameter q over parameter r ($r = 1, \ldots, l$);
- l is the number of parameters;

Then, the design-based complexity factor $Cf_{D,i}$ can be obtained by applying Eq. (9).

Both the complexity factors, $Cf_{P,i}$ and $Cf_{D,i}$, are used as predictors of DPU occurring in each workstation. Previous research in the electromechanical field established that the relationship between *DPU* and Cf_P and Cf_D follows a power-law behavior (Galetto et al. 2020; Verna et al. 2021, 2020a), according to Eq. (7).

Since low-volume productions are typically characterized by very long product life cycles, acquiring enough data to build a robust model may not be straightforward. Therefore, in this study, a self-adaptive model is proposed. Two different approaches can be used to this aim. The first one requires that the most up-to-date DPU values be considered and added to the existing data collection to refine the parameter estimates of the regression model. On the other hand, a second approach avoids working with old data, which may be distant from the current defectiveness state. In particular, defined a certain period, a "moving fitting" of the model could be performed, which considers only the most recent data of such a moving period. For instance, if the model to be built needs to consider the data of one production year, only the last year's data will be used to update the model parameters, neglecting the previous ones. The selection of the most suitable approach depends on the assembly process under consideration and related defectiveness data. The second approach is to be preferred to the first one when the process is not in a stationary condition, e.g., in the start-up phase of the process. In the case study proposed in the following section, the first approach is adopted. Accordingly, the most up-to-date DPU values are added to the existing dataset to refine the parameter estimates of the regression model reported in Eq. (7). This approach allows having a self-adaptive model fed by the "new knowledge" acquired during its operation. Clearly, the more data used to estimate model coefficients and the greater the periodicity of self-adaptation, the greater the accuracy of the model itself.

It has to be noted that the proposed model, which combines the approaches proposed by Shibata (2002) and Su et al. (2010), can be applied to the majority of assembly processes. Indeed, the design-complexity factor of Shibata model was specifically designed for electronic devices due to the use of DAC method employed in Sony Corporation, see Eq. (4). On the other hand, Su model was designed for copier products and did not consider the logarithmic transformation bias occurring when predicting low defect rates (Galetto, Verna, and Genta 2020). Thus, applying such models in contexts other than those for which they were designed may not be so straightforward, as refinements or amendments may be required. On the contrary, the novel approach proposed in this study allows estimating product defectiveness for any electromechanical product, as there are no parameters designed for specific fields of application.

3.1. Model development for wrapping machine assembly

Wrapping machines are equipment able to wrap palletized loads, typically regularly shaped, at the end of a line of production processes. In this case study, the rotating ring wrapping machine produced by the Italian company Tosa Group S.p.A. is considered (see Fig. 1a). Typically, about 50 units are assembled in a production year, and each machine may be highly tailored according to the customer's requirements. In particular, a single part of the machine is analyzed: the pre-stretch device (circled in Fig. 1a). Such an electromechanical device, which is common to all rotating ring wrapping machines, is used to (*i*) pull/unwind the plastic film, (*ii*) pre-stretch and position the plastic film, (*iii*) perform the necessary number of windings. The 3D Cad model of the device is shown in Fig. 1b, including the list of its main component.

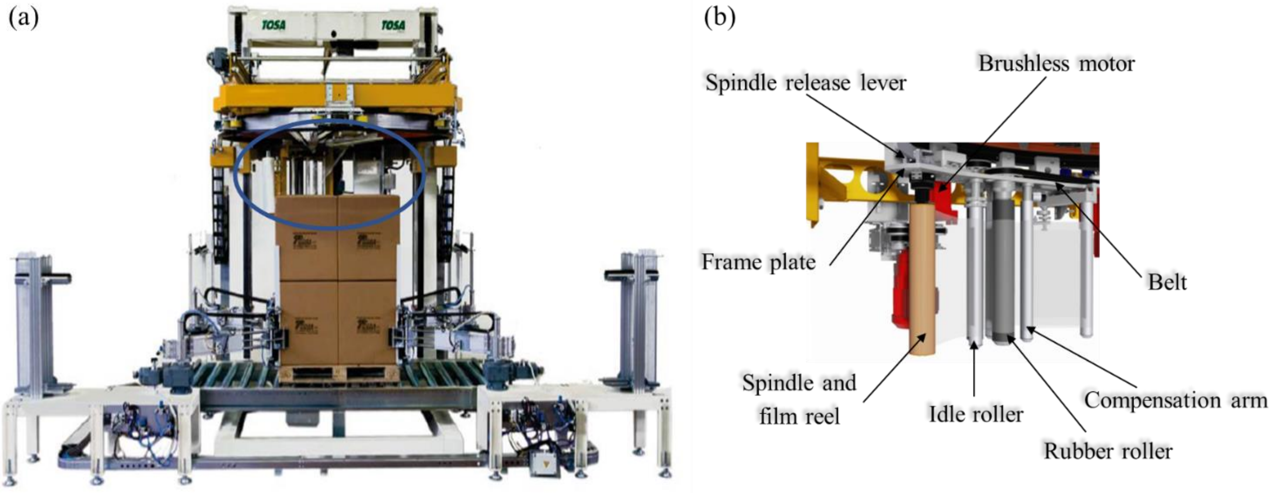

Fig. 1. (a) Rotating ring wrapping machine of Tosa Group S.p.A. (Italy); (b) 3D CAD model of the pre-stretch device and its main components.

According to the model proposed in Section 3, the assembly of the pre-stretch device is subdivided into m=29 workstations. In the first 9 workstations, the subassemblies are assembled on the bench. From workstation 10 to 29, the assembly is performed on the frame plate, as detailed in Table 2. Table 2 also reports the experimental DPU_i values collected during a typical production year in nominal working conditions.

Table 2. Subdivision of the assembly process of a pre-stretch device of a wrapping machine into workstations (WS) and experimental DPU_i values (referring to one production year).

WS no.	Workstation description	Experimental DPU_i (one production year)
1	Motor no. 1 bench assembly	0.0364
2	Motor no. 2 bench assembly	0.0364
3	Support plate of motor no. 2 bench assembly	0.0182
4	Spindle bench assembly	0.0000
5	Rubber tyres bench assembly	0.1091
6	Idle rolls bench assembly	0.0545
7	Rubberized pads bench assembly	0.0000
8	Belt tensioner device bench assembly	0.0364
9	Driven wheels of transmission system bench assembly	0.0000
10	Pre-stretch frame plate preparation	0.0182
11	Rubber rollers on pre-stretch frame plate assembly	0.0182
12	Idle rollers on pre-stretch frame plate assembly	0.0182
13	Motor no. 1 on frame plate assembly	0.0000
14	Transmission system of motor no. 1 assembly	0.0000
15	Motor no. 2 on frame plate assembly	0.0182
16	Transmission system of motor no. 2 assembly	0.0364
17	Motor no. 1 bracket on pre-stretch frame plate assembly	0.0000
18	Belt tensioner on pre-stretch frame plate assembly	0.0364
19	Transmission system of motor no. 1 calibration	0.0364
20	Transmission system of motor no. 2 calibration	0.0364
21	Spindle preparation for assembly on pre-stretch frame plate	0.0000
22	Spindle group on pre-stretch frame plate assembly	0.0364
23	Rubber pads on pre-stretch frame plate assembly	0.0000
24	Motor assembly no. 1 final steps	0.0545
25	Motor assembly no. 2 final steps	0.0545
26	Spindle release lever bench assembly	0.0000
27	Spindle release lever on pre-stretch frame plate assembly	0.0000
28	Compensation arm bench assembly	0.0909
29	Compensation arm on pre-stretch frame plate assembly	0.0000

For each i-th workstation, the two predictors of the model, $Cf_{P,i}$ and $Cf_{D,i}$, are obtained by Eq. (10) and (9), respectively. To estimate the first predictor, each workstation is subdivided into elementary operations, and the related standard time is obtained by considering an average time of three measurements. The threshold assembly time, t_0, is set equal to 0.04 min, corresponding to the time to complete the least complex elementary operation in the whole assembly process. Regarding the second predictor, l=11 parameters are selected from those listed in Table 1 (see Table 3). The weights w_q of the parameters are calculated by Eq. (11) by considering the individual evaluations of $e = 6$ evaluators (2 assembly engineers and 4 assembly operators), who also estimated the degrees of difficulty, A_{kqi}. As a result, the process and the design-based complexity factors, $Cf_{P,i}$ and $Cf_{D,i}$, derived by Eq. (10) and (9), respectively, are reported in Table 4 for each i-th workstation.

Table 3. Design parameters in the assembly of wrapping machines.

Parameter	Description	$\left(\prod_{r=1}^{l} \alpha_{qr}\right)^{\frac{1}{l}}$	Weight w_q
P1	Shape of mating objects	1.761	0.139
P2	Force required	1.529	0.120
P3	Alignment of components	1.907	0.150
P4	Mating direction	2.151	0.169
P5	Ratio of the mating component's weight to the mated one	1.192	0.094
P6	Ratio of length to width (diameter) of the mating component	1.161	0.091
P7	Reachability to the assembled component	0.714	0.056
P8	Mating component's length,	0.810	0.064
P9	Amount of support required for the assembly	0.466	0.037
P10	Stability of the resultant assembly	0.523	0.041
P11	Length of components intersection	0.480	0.038
	$\sum_{q=1}^{l}\left(\prod_{r=1}^{l} a_{qr}\right)^{\frac{1}{l}}$	12.693	

The best-fitting model, describing the relationship between DPU_i and the two predictors, $Cf_{P,i}$ and $Cf_{D,i}$, is the power-law regression model, in the form shown in Eq. (7). The analysis was performed in the software *MINITAB®* by using nonlinear regression. This experimental finding corroborates previous research in the electromechanical field (Galetto et al. 2020), and confirms that the power-law model is suitable not only for mass production (Shibata 2002), but also for low volume production. The defect prediction model is as follows:

$$DPU_i = 5.04 \cdot 10^{-5} \cdot (Cf_{P,i})^{0.77} \cdot (Cf_{D,i})^{3.08}. \tag{12}$$

The analysis of the residuals between experimental *DPU* and predicted *DPU* suggests that the power-law model describes well the trend of the *DPU* as a function of the assembly complexity. The visual analysis of the residues was accompanied by a statistical normality test, the Anderson-Darling test, whose result is that the normal distribution cannot be rejected with a confidence level of 95% (Devore 2011). The *S* value, i.e., the standard error of the regression, is equal to 0.024. It represents a measure of goodness of fit of the model to be used instead of R^2 for nonlinear models (Bates and Watts 1988). Such a value indicates that the experimental values of *DPU* fall an average distance of 0.024 units from the *DPU* values predicted by Eq. (12).

To refine model parameters, DPUs collected over a further six months were added to DPU values related to one year of production. Therefore, the new data analyzed refer to a year and a half of production (about 80 machines). Such values are reported in Table 4. The new prediction model is as follows:

$$DPU_i = 3.87 \cdot 10^{-4} \cdot (Cf_{P,i})^{0.67} \cdot (Cf_{D,i})^{2.01}. \tag{13}$$

Again, the analysis of the residuals between experimental *DPU* and predicted *DPU*, and the Anderson-Darling test, at a significance level of 5%, lead not to reject the hypothesis of normality of the residuals. In this case, the *S* value is increased to 0.026, showing that the experimental values of *DPU* fall a standard distance of 0.026 units from the *DPU* values predicted by Eq. (13).

A comparison of the 95% confidence intervals of the parameter estimations of the two models (Eq. (12) and (13)) is provided in Fig. 2. In all three cases, the confidence intervals of the parameters of the two models are compatible. In addition, the width of the confidence intervals decreases for parameter k_1, while slightly increases for parameters k_2 and k_3.

Table 4. Defect prediction model variables of the pre-stretch device assembly.

WS no.	$Cf_{P,i}$ [min]	$Cf_{D,i}$	DPU_i predicted by Eq. (12)	Experimental DPU_i (1 year and 6 months of production)	DPU_i predicted by new Eq. (13)
1	7.1	4.4	0.0214	0.0361	0.0277
2	7.4	4.6	0.0250	0.0361	0.0309
3	5.8	5.1	0.0287	0.0120	0.0325
4	3.8	4.3	0.0126	0.0000	0.0177
5	11.9	5.7	0.0715	0.1084	0.0664
6	7.7	4.9	0.0320	0.0602	0.0366
7	3.5	2.8	0.0030	0.0000	0.0069
8	2.4	3.5	0.0045	0.0361	0.0084
9	0.3	3.7	0.0012	0.0000	0.0025
10	4.8	4.2	0.0142	0.0361	0.0199
11	5.2	5.3	0.0312	0.0241	0.0336
12	5.7	5.1	0.0298	0.0120	0.0331
13	3.7	5.1	0.0205	0.0000	0.0241
14	0.9	5.4	0.0084	0.0000	0.0106
15	8.5	4.9	0.0355	0.0241	0.0398
16	0.8	4.9	0.0060	0.0361	0.0084
17	0.9	4.2	0.0041	0.0000	0.0067
18	1.7	4.3	0.0067	0.0361	0.0103
19	5.7	5.2	0.0306	0.0361	0.0338
20	6.3	5.2	0.0332	0.0361	0.0361
21	2.2	5.2	0.0147	0.0000	0.0177
22	13.4	5.6	0.0738	0.0361	0.0692
23	2.3	4.1	0.0075	0.0000	0.0116
24	1.1	4.1	0.0041	0.0482	0.0070
25	1.2	4.3	0.0049	0.0482	0.0078
26	1.2	4.1	0.0042	0.0602	0.0071
27	7.9	4.7	0.0293	0.0000	0.0347
28	12.2	5.5	0.0672	0.0964	0.0641
29	5.4	5.0	0.0257	0.0000	0.0299

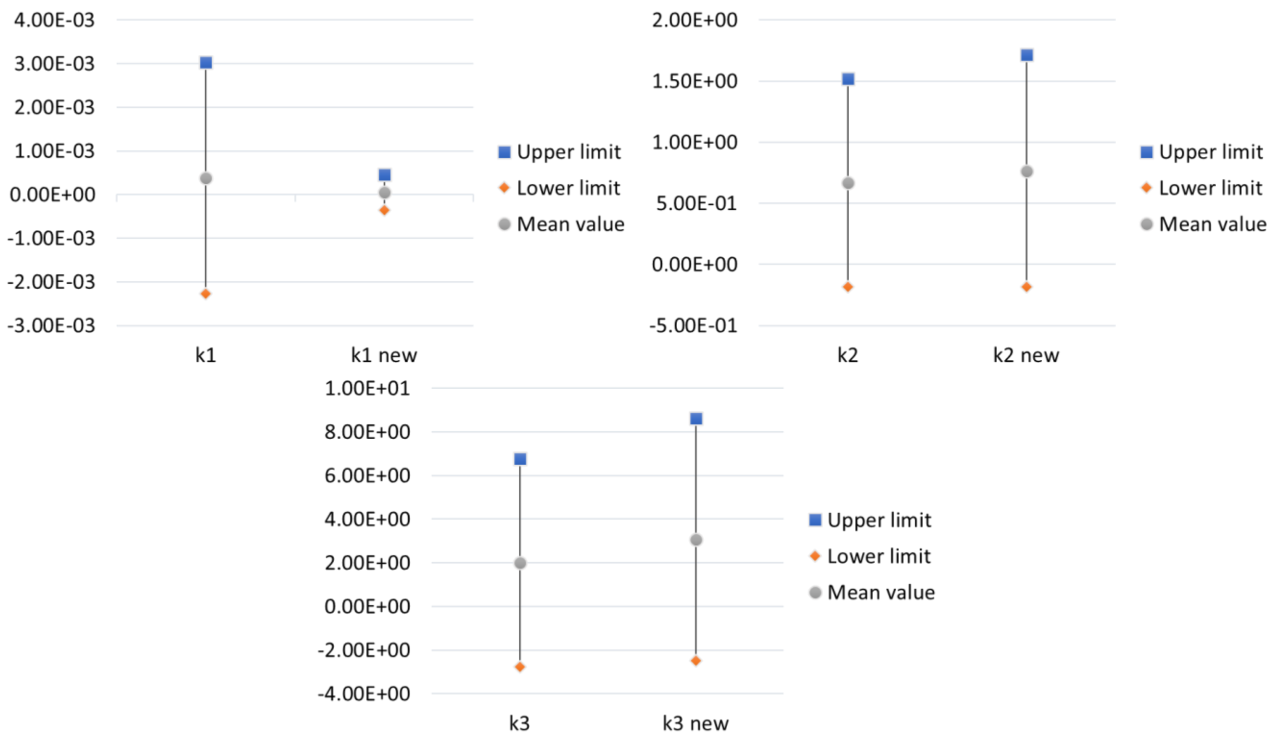

Fig. 2. Comparison of 95% confidence intervals of the parameter estimates of the two models, see Eqs. (12) and (13).

4. Diagnostic tool to identify critical assembly workstations

In this section, a diagnostic tool to detect critical workstations is developed, using the self-adapting defect prediction model described in Section 3. Such a tool uses the model as a reference of the average defect rate (DPU) found in a workstation and, in addition, exploits the corresponding uncertainty range. In detail, to each predicted DPU_i obtained through the prediction model, it is possible to associate two prediction limits. These limits constitute the thresholds for identifying critical workstations in terms of defectiveness which are caused by special causes of variation - therefore, variations coming from sources not common to the process (Montgomery 2012). The approach may be summarized in the following steps:

1) Defects detected in each workstation over a specific period of time are divided by the number of units inspected to obtain the observed DPU_i values. It has to be remarked that, on such data, it is always advisable to perform a preliminary data analysis using traditional statistical techniques for outliers detection and filtering (Barbato, Germak, and Genta 2013).
2) The prediction limits of each DPU_i value are derived according to the following equations:

$$UPL_i = DPU_i + t_{1-\frac{\alpha}{2},\nu} \cdot \sqrt{VAR(DPU_i) + S^2} \tag{14a}$$

$$LPL_i = DPU_i - t_{1-\frac{\alpha}{2},\nu} \cdot \sqrt{VAR(DPU_i) + S^2}, \tag{14b}$$

where:

- UPL_i is the upper prediction limit and LPL_i is the lower prediction limit of DPU_i;
- $t_{1-\frac{\alpha}{2},\nu}$ is the value of Student's *t* distribution with ν degrees of freedom and significance level α;
- $VAR(DPU_i)$ is the variance of the DPU_i, calculated by using the average values of the regression parameter estimates, their standard deviations and the correlation matrix for parameter estimates, according to Eq. (15):

$$VAR(DPU_i) \approx \left[\frac{\partial DPU_i}{\partial \boldsymbol{K}}\right]^T \cdot cov(\boldsymbol{K}) \cdot \left[\frac{\partial DPU_i}{\partial \boldsymbol{K}}\right], \tag{15}$$

  where $\boldsymbol{K} = [k_1, k_2, k_3]^{\mathrm{T}}$ is the vector of regression parameters of Eq. (7) and $cov(\boldsymbol{K})$ is the variance-covariance matrix of regression parameters, both estimated by applying the Gauss-Newton method implemented in the software *MINITAB*® to the model of Eq. (7) (Bates and Watts 1988).
- S is the standard error of the estimate, also known as the standard error of the regression, derived from the sum of the squared residuals *RSS*, the number of observations *N* and the number of free parameters *P* - 3 in the case of the proposed defect prediction model of Eq. (7), according to Eq. (16) (Bates and Watts 1988):

$$S = \sqrt{\frac{RSS}{N-P}}. \tag{16}$$

1) The observed DPU_i values are compared with the corresponding prediction limits:
   a. If the observed DPU_i falls within the prediction range (LPL_i, UPL_i), the workstation is not detected as critical.
   b. If the observed DPU_i is higher than the upper prediction limit (UPL_i), it means that an abnormal defectiveness is occurring in such workstation, and accordingly, the workstation is to be signaled as critical.
   c. If the observed DPU_i is below the lower prediction limit (LPL_i), the workstation is also to be signaled as critical due to the low defect rate observed, which might be due to quality inspection errors (false negatives).

Therefore, the proposed diagnostic tool aims at detecting abnormal workstations and can be implemented whenever new observed DPUs are available on each workstation. In this view, the tests carried out may be seen as in-progress controls.

4.1. Practical application to wrapping machines assembly

The diagnostic tool described in Section 4 is applied to detect critical workstations in the assembly of wrapping machines. In such a case, the defect prediction model developed in Section 3.1 is used as the reference model. Table 5 reports the upper and lower limits of the 95% prediction interval of the defects per unit in each *i*-th workstation (DPU_i), calculated by considering the model built with the data of one year of production (see Eq. (12)) and the refined model that considers the additional data of the last 6 months (see Eq. (13)). To obtain the prediction limits, the variance of DPU_i is calculated according to Eq. (15), for both the models, as reported in Table 5. Then, Eqs. (14a) and (14b) are applied by considering $t_{1-\frac{\alpha}{2},\nu} = t_{1-\frac{0.05}{2},26} = 2.055$, as the degrees of freedom $\nu = 26$ are obtained by subtracting the number of estimated model parameters (i.e., k_1, k_2 and k_3) from the total number of workstations (m=29). Moreover, as mentioned in Section 3.1, S=0.024 in the first model and S=0.026 in the second model. It should be noted that negative values of LPL_i are set equal to zero in Table 1. Accordingly, for most workstations, the prediction interval is not symmetric with respect to the predicted DPU_i.

The diagnostic tool is applied to the DPU derived by collecting the defects occurring in each workstation over a period of 6 months (corresponding to 28 pre-stretch devices), which are also reported in Table 5. According to the step 3 illustrated in Section 4, each DPU_i (last column of Table 5) is compared with the 95% prediction limits obtained for both models. It is found that workstations 10 and 26 are detected as critical workstations when considering the model of Eq. (12), because DPU_i values are higher than the corresponding UPL_i. On the other hand, when considering the refined model of Eq. (13), only workstation 26 is identified as critical. The difference in the two diagnostic tests is due to the refined model of Eq. (13), being more representative of the actual process defectiveness.

Table 5. Variance, lower and upper 95% prediction limits of DPU_i, considering the model of Eq. (12) and the refined model of Eq. (13), and observed DPU_i values of the last 6 months.

WS no.	Model - Eq. (12)			New model - Eq. (13)			Observed DPU_i (last 6 months)
	$VAR(DPU_i)$	LPL_i	UPL_i	$VAR(DPU_i)$	LPL_i	UPL_i	
1	1.05E-04	0.0000	0.0755	1.22E-04	0.0000	0.0864	0.0357
2	9.43E-05	0.0000	0.0788	1.00E-04	0.0000	0.0889	0.0357
3	3.79E-05	0.0000	0.0802	3.93E-05	0.0000	0.0882	0.0000
4	3.21E-05	0.0000	0.0639	4.41E-05	0.0000	0.0735	0.0000
5	2.08E-04	0.0134	0.1295	2.14E-04	0.0044	0.1283	0.1071
6	5.84E-05	0.0000	0.0843	5.68E-05	0.0000	0.0929	0.0714
7	2.11E-05	0.0000	0.0538	7.85E-05	0.0000	0.0640	0.0000
8	1.56E-05	0.0000	0.0551	3.81E-05	0.0000	0.0640	0.0357
9	1.86E-06	0.0000	0.0512	6.69E-06	0.0000	0.0569	0.0000
10	5.20E-05	0.0000	0.0663	7.03E-05	0.0000	0.0767	0.0714
11	9.33E-05	0.0000	0.0849	8.97E-05	0.0000	0.0912	0.0357
12	4.47E-05	0.0000	0.0815	4.62E-05	0.0000	0.0891	0.0000
13	6.18E-05	0.0000	0.0730	6.78E-05	0.0000	0.0809	0.0000
14	8.67E-05	0.0000	0.0618	1.09E-04	0.0000	0.0689	0.0000
15	7.02E-05	0.0000	0.0883	6.80E-05	0.0000	0.0965	0.0357
16	3.56E-05	0.0000	0.0573	5.59E-05	0.0000	0.0646	0.0357
17	1.03E-05	0.0000	0.0544	2.23E-05	0.0000	0.0617	0.0000
18	1.58E-05	0.0000	0.0573	2.85E-05	0.0000	0.0655	0.0357
19	5.08E-05	0.0000	0.0826	5.20E-05	0.0000	0.0899	0.0357
20	4.72E-05	0.0000	0.0850	4.89E-05	0.0000	0.0921	0.0357
21	8.84E-05	0.0000	0.0682	1.02E-04	0.0000	0.0757	0.0000
22	2.16E-04	0.0155	0.1322	2.31E-04	0.0066	0.1317	0.0357
23	1.75E-05	0.0000	0.0581	3.06E-05	0.0000	0.0669	0.0000
24	9.31E-06	0.0000	0.0544	2.06E-05	0.0000	0.0619	0.0357
25	1.24E-05	0.0000	0.0553	2.50E-05	0.0000	0.0629	0.0357
26	9.42E-06	0.0000	0.0545	2.08E-05	0.0000	0.0620	**0.1786 (*)**
27	8.75E-05	0.0000	0.0828	8.72E-05	0.0000	0.0921	0.0000
28	1.49E-04	0.0113	0.1230	1.68E-04	0.0037	0.1244	0.1071
29	3.61E-05	0.0000	0.0771	3.77E-05	0.0000	0.0855	0.0000

According to the diagnostic test results, the process engineers may carry out specific and accurate checks. The anomalous defectiveness found in workstation 26, marked in Table 5 with an asterisk, is due to the use of a batch of a mechanical component to assemble the spindle release lever, purchased from an external supplier, which turned out to be out of tolerance. On the other hand, as regards workstation 10, DPU of the last 6 months, which were defined as physiological using the most up-to-date model, are due to the bad finishing of the frame plate holes, an operation that is carried out manually by the operator using a manual grinding machine. This inevitably produces defects that are due to the process itself and the type of operation performed, and not to special causes of variation. In light of these results, the defect prediction model to be used for future diagnostic tests should not consider the defects of the last months for workstation 26, because they are caused by special causes of variation, and therefore are not representative of the physiological defectiveness of the process.

5. Conclusions

Achieving Zero-Defect Manufacturing (ZDM) goals is key in manufacturing organizations to maintain their position in the marketplace. One of the strategies of ZDM is the detection of defects. In low-volume assembly processes, the scarcity of historical data and the non-applicability of traditional statistical process approaches make defect detection and prevision a remarkable issue. In this investigation, the aim is to propose a novel diagnostic tool to identify critical workstations based on the formulation of a probabilistic model for defect prediction. The proposed methodology involves the decomposition of the assembly process into workstations, in which a specific operation is performed. Then, a prediction model relating the observed defects per unit (*DPU*) in each workstation and the level of complexity in terms of the assembly process and design is developed. Such a model can be defined as self-adaptive as its parameters are continuously refined as new data becomes available from the process. This diagnostic tool exploits such a prediction model and its variability to identify critical workstations. In detail, the workstations whose defectiveness deviates, at a specific confidence level, from the predicted value can be easily identified by verifying whether the observed *DPU* value does not fall within the prediction interval. Consequently, engineers are guided to recognize the special causes of variation of such abnormal defectiveness to undertake appropriate corrective actions. The conceptual presentation of the approach is supported by a practical application in the assembly of low-volume production of wrapping machines.

The potential of the proposed method lies in the ease of application in real contexts and the speed of identification of critical steps of the production process. However, some issues that may arise when a practitioner or researcher applies the method to real cases are summarized below. Firstly, the process should be appropriately decomposed into elementary operations and workstations in order to comply with the assumption that the total number of possible defects within a certain workstation is at most equal to the total number of elementary operations in the same workstation. Secondly, to estimate the design-based complexity factor, the design parameters (see Table 3) should be carefully selected according to the case study considered. Furthermore, expert evaluations are critical to obtaining an accurate estimate of the complexity of the design, so it is necessary to guide experts through the evaluation of weights and degree of difficulty. Once the defect prediction model has been defined, the implementation of the diagnostic tool is straightforward and does not involve any particular operational issues.

The proposed diagnostic tool is subject to some limitations. First of all, a defect prediction model should be available. Thus, an initial historical dataset of the defectiveness of the process is necessary. However, in the modern industrial context, the increasing use of widespread sensor technology and online control systems allows a real-time acquisition of data to be used as preliminary inputs. Therefore, this limitation may be partially overcome. Secondly, the generalizability of the proposed approach is subject to certain restrictions. The model is suitable for electromechanical assemblies. As a first approximation, if a specific defect prediction model is not available, the proposed model may be adopted for other products belonging to the electromechanical field, without any particular amendments. Then, once new data are collected, the model can be updated to make it more representative of the specific process considered.

In the future, some research will be devoted to overcoming (at least in part) the above limitations. In addition, the proposed diagnostic tool will be enhanced through the use of Machine Learning (ML) techniques, thus increasing the effectiveness and timeliness of diagnosis. Finally, further research will be conducted to monitor workstation defectiveness over time to complement the diagnostic control proposed in this study, adopting, for example, specific DPU-control charts.

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