APIS
Automatic Packaging Inspection System

Carlos A. Charles Gómez
Master of Engineering in Manufacturing Engineering
Advisor: Edgar Torres, Ph.D.
Industrial and Systems Engineering Department
Polytechnic University of Puerto Rico

Abstract *— Blister packaging is very common and very popular in the pharmaceutical and medical devices industry. This high increase in the use of this type of packaging provides a large variety of designs for cosmetic appearance and at the same time it has become more important to ensure the integrity of the packaging for the safety and the health of the patients using the products. Quality inspections are one of the most important areas of any manufacturing process and there are many ways to inspect the quality and integrity of these packages to provide and to ensure that the quality complies with the regulation and standards. In the other hand, vision system inspection is improving and very flexible and powerful to perform any kind of visual inspections for quality, measure and even temperature and others. This article focusses on how is the possibility of a vision system to inspect blister packaging to prevent packaging leaks, sealing and damage foil and what type of effectiveness or consistency it would have to be reliable.*

Key Terms *— Blister Packaging, Packaging Inspection, Vision Systems.*

INTRODUCTION

Millions of contact lenses are produced and packed in blisters every month. These blisters are designed and used to protect the lenses by keeping the solution and the lens sterile and protected for the patient safety. Any issue that affects the package integrity and quality can lead to an adverse effect in the product shelf life, microorganism growths and lenses out of parameters, which in any case can endanger the patients' health.

There are many blisters designs, different foil materials, blister materials, and sealing methodologies or parameters to meet the criteria defined for each blister and foil combinations to keep the product integrity by design. In addition, there are many ways in which a blister could be incorrectly sealed or damaged, causing a critical quality related issue. To inspect these sealed blisters there are visual methods and manual destructive methods that are not 100% reliable as the inspected blisters are samples selected randomly by statistical sampling. This type of inspection could allow some defects to reach the patients after all the product manufacturing and quality inspections performed. As part of these tests are included many manual destructive methods to determine the sealing width and effectiveness of the sealing dies to determine any kind of maintenance required to try to predict and avoid any leakage or bad sealing due to sealing dies debris wear or damage. A negative result in the final sampling quality inspection of the blister samples within a manufacturing lot can cause several other lots to be bound and hold their process.

The main problem with this type of inspection is that is done based on samples inspection in which sampling data that is not 100% accurate and all the inspections are done by subjective interpretation criteria done by human. Even though there are specific procedures and criteria to perform this type of inspections, it still inconsistent depending on the personnel inspecting.

RESEARCH OBJECTIVES

The main objective of this design project is to develop a vision system to effectively inspect the integrity of and quality of a Foil/Blister packaging and to provide real time 100% and more reliable decisions without human intervention.

RESEARCH CONTRIBUTIONS

This project supports the Company's goal of operational excellence with zero NCR and to reduce the cost of quality by providing a 100% real time packaging inspection.

Currently the Quality Inspection to the foil/blisters packaging is standardized and performed to all the manufacturing lots with a define frequency. It is performed manually by specialized quality area personnel, but even though it is an approved sampling plan, sealed blisters are passing through the process with sealing and packaging defects. For such reason this system will contribute in reducing the cost associated to 100% manual inspection process when a defect is detected during the sampling inspections. In addition, it will contribute in the following:

- A leaner process without in-line manual inspections
- 100% product inspection for damage foil
- 100% product inspection for variable information
- 100% real time sealing area defects monitoring to provide information of sealing degradation or consistent sealing defect indicating the correct moment to clean the sealing dies instead of cleaning every lot.

RESEARCH BACKGROUND

This design project was conducted in a Medical Devices Company located in Juana Diaz, Puerto Rico. One of the main concerns the Company is facing now-a-days is the cost of quality related to packaging, as this is considered a good device being rejected by its package. Also, the possible complains and patients' dangers associated to any possible defect caused by packaging integrity.

During the latest quarters of fiscal year 2016 packaging defects found in the final quality inspection increased from previous findings of 2016 quarters. It was found that the current major offender for these packaging defects was "Leaks" defects. The "Leaks" defect could be caused for various reasons in the package. The different defects to be inspected in a blister are divided in different categories. These categories are found in the following charts represent the distribution of the different defects by severity and quarter.

Quality control is important in any manufacturing and production process. Sometimes the methods used to inspect and test for quality control are very time consuming and difficult to perform, leading to allow defective product to be incorrectly classified as good product or rejecting a lot of good product, which affects the profitability of any production or manufacturing line. In a float glass factory this is not the exception, by example, the quality control is crucial because defects found in the glass could depress the grade of the glass causing the factory to potentially loss sell money. It has been found that human inspector performing the quality control inspections for the glass cannot perform the inspections in timely manner to prevent or detect most of the possible defects to be inspected for. Taken this glass factory problem into consideration, the team of [1] Xiangqian Peng, Youping Chen, Wenyong Yu, Zude Zhou and Guodong Sun (2007) design and provided "An online defects inspection method for float glass based on machine vision" in which distributed inspections were performed through the glass detecting changes of image gray levels caused by difference in optic character glass and defects. To be able to create this method a series of image processing algorithms were set up and reliability, veracity and real-time processing were selected as major requirements.

This team could demonstrate the effectiveness of machine vision as inspection method by improving the accuracy and reliability of the quality control of the factory.

Another case in which the quality control is even more important is the case of the pharmaceutical blister packaging for tablets or capsules. In this case most of the tests performed are destructive like sophisticated gauging methods and vacuum leak testing to test the seal integrity of the blister pack. This type of quality control still requires being by random sampling due to its destructive nature. In an article of [2] "Vision helps make blister packs safer" in Vision Systems Design magazine (May 2007), David Lieberman presents the information of developed system by Packaging Technologies & Inspection (PTI) that combines vacuum leak and machine vision for a continues nondestructive test methods. In this case the vision system was not implemented alone, requiring the vacuum leak testing to create a physical change in the package to create visual difference between the good blisters pockets and the bad blisters pockets. The vision system then is used to process the image and identified with the inspection algorithms the good and bad products to handle by the system and reject the bad ones.

To use vision systems for defects inspection we also required to measure the defects and categorized them to visually describe the possible defects to be found and compare them with the acceptance criteria required for the process. There are certain special characteristics of the process in which the inspection could consists of the geometry or pattern present in a product or package, position of certain regions, or even the size of certain areas or patterns inside the product or package to be inspected. An implementation by [3] J.Q. Gao and C.S. Wu (2007 Science & Technology of Welding & Joining) in which the team developed a "Vision based measuring system for both weld pool and root gap in continues current GTAW", they were able to provide a low-cost measuring system to detect the weld pool geometry and the root gap at the same time. Using grey level distribution characteristics to be analyzed they could develop image processing algorithms to extract the weld and root gap edges effectively in order to inspect the track of the welding and the penetration for quality control and machine control purposes. As seen it is very critical, important and very useful depending of the application. The measuring capabilities and the most detailed calibration could be required in some applications, but not all of them. In certain cases it is the most important purpose of the vision system as presented in the [4] "Research on Accuracy of Automatic Systems for Casting Measuring" (2016), in this research J.Jaworski, R.Kluz and T.Trzepiecinski consisted of ensuring the required quality of casting of a production process. In this case using a six-axis robot and an optical measuring system to go around the production parts and be able to provide a 3D inspection of the part for defects and correct dimensions. In this case the criticality of the accuracy of the robot is very important as well, as this can affect the selected region to be inspected by the optical measuring system (vision system). They were able achieved the goal of the research with one significant advantage of a non-contact measuring system and real-time quality control by being able to inspect and measures for quality control during early stages of the manufacturing process simultaneously of parts manufacturing.

RESEARCH METHODOLOGY

The methodology followed in this project was the DMAIC improvement cycle as per Figure 1, which stands for: Define, Measure, Analyze, Improve and Control

FIGURE 1
DMAIC Model

DMAIC is the core tool to drive Six Sigma projects and has been very successful because it provides a series of specific steps to provide solutions and controls to improve a process objectively with data.

DEFINE - The purpose is to clearly understand and explain the business problem, the scope of the project and the timeline and set the project team to comply with the timeline. Several activities are performed during this step which includes project charter, data about the problem, customer data, plan, voice of the customer and others.

In this project, the number of lots with nonconformance during final quality inspection was the source of the information.

MEASURE – The purpose is to objectively establish current baselines as the basis for improvement. The stage is mainly based on data collection. The performance metric baseline will be compared to the performance metric after the project to objectively determine if the project was successful by significantly increasing or reducing the impacted metric.

The Measure tool used in this project was the Pareto Chart, one of the most common tools used to help focus a team's effort on the biggest contributors to a problem. In a Pareto Chart each bar represents a different element of a problem. That means you can solve most of the problem if you take care of the issues represented by the tall bars. A Pareto chart helps you decide where your improvement efforts will have the biggest payoff, and can be used only when the problem under study can be broken down into categories and the number of occurrences can be counted for each category as per Figure 2.

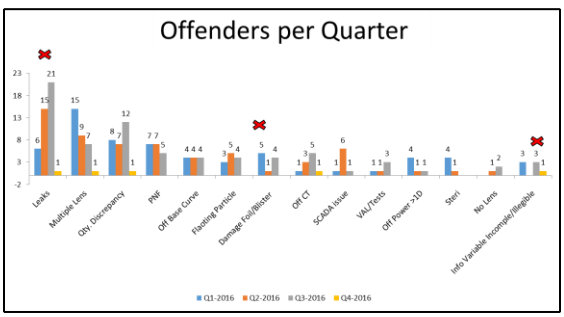

Figure 2
Final QA Pareto

ANALYZE -The purpose of this phase is to identify, validate and select root causes for elimination. An additional data collection is often required to understand the contribution of the possible root causes and make and set the priorities to improve. Some of the analyze tools used in this project was the Pareto charts and Process Maps. The use of Pareto charts and Sub-Pareto charts during this phase provided the required information to focus in the "leaks "defect as our main priority after being categorized as the main offender for Final QA inspections (see Figure 2). The Sub-Pareto chart provided the required information to understand and focus on certain specific leaks defect root causes being categorized after manually inspecting and categorizing each of the leaks defects into sub categories, as per Figure 3.

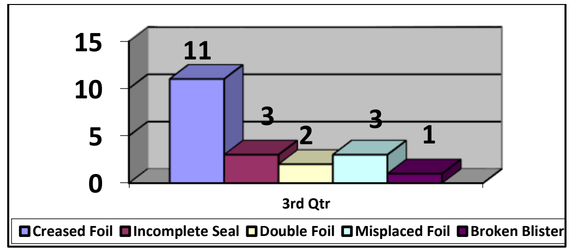

Figure 3
Sub Pareto for Leaks

IMPROVE- The purpose of Improve is to make changes in a process that will eliminate the defects, waste, cost, etc., which are linked to the customer need identified in the Define stage. Team must be sure that the changes they make must affect the causes they confirmed in Analyze.

To improve the Final QA results to comply with the objective of the project a vision system was proposed to provide 100% blister packaging inspection and reduce or eliminate the main quality offender. After Analyze phase completed with a deep understanding of the variety of defects causing leaks it was proceeding to gather all the available blisters packages rejected in Final QA as samples to be inspected and classified for the development the vision system. A prototype was built and images were taken for every rejected sample, see Figure 4.

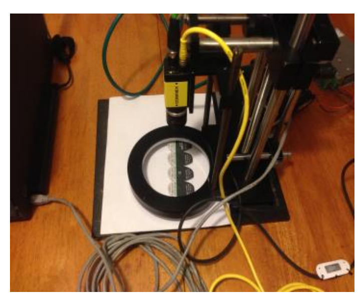

Figure 4
Vision System Prototype

Several illuminations trials and image processing techniques and algorithms had to be applied to the images due to the bright generated by the foil into the images. This was necessary to be able to inspect the sealing area and to identify possible defects as per Figure 5.

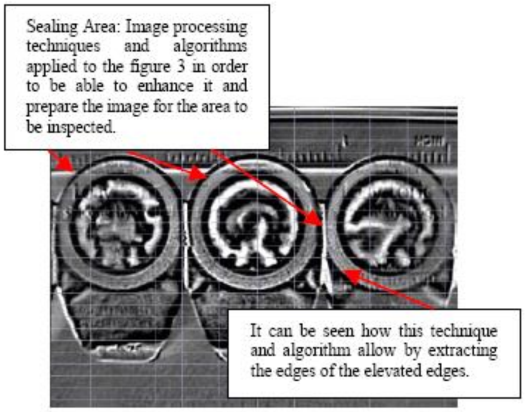

Figure 5
Images from the Prototype VS

All the rejected samples previously collected from Final QA were processed through the prototype to capture the images and provide image classification to each de It can be seen how this technique and algorithm allow by extracting the edges of the elevated edges. of blisters packaging ide lso processed through the prototype to be classified as good by the prototype.

CONTROL -The purpose of this phase is to sustain the improved metrics. Improvements are monitor and the creation of guidelines, procedures, setup tools or maintenance procedures and schedules are implemented to ensure the process do not become unstable.

RESEARCH RESULTS

As part of the test performed to confirm the vision system effectiveness and consistency for correct blister packaging inspection it was defined a sampling plan of (n = 288; a = 0; r = 1; AQL = 0.018%, LTPD:0.80). This sampling plan was used for good blisters and the rejected samples. To develop the software algorithms and setup the system in the most reliable manner to don't reject the good blisters and to ensure it is able to reject the visible already rejected defects. During the first test performed the vision system could effectively and consistently inspect and pass the 288 good blisters packaging providing a reliable result and confirming that the system won't cause additional yield losses. In the second test performed with 288 rejected samples the system could perform as expected and effectively inspected and failed the 288 identified as bad blisters packaging.

CONCLUSIONS

During the two final tests performed with sampling plan selected with a sample size 288 samples for each of the test with results of zero (0) in both tests runs it can be concluded that the vision system and the setups applied in the prototype is reliable and effective to consistently inspect 100% of the production in line and to provide a huge improvement to Final QA inspection findings by detecting and rejecting these defects in the manufacturing line. Also, it proved that other techniques can be applied to improve quality and provide safer devices and products to the patients and clients by providing vision system and in line automatic inspections in the manufacturing lines to provide objective and consistent defect detection and rejection. In the other hand, the system was only able to inspect and reject all the visible defects already identified as visible defects and in the specific area in which the camera is focused. It is important to understand that the process will be leaner and the results has demonstrated that these defects will be catch in the manufacturing line, but this system is not designed to catch all the existing defects neither unknown defects.

FUTURE PROJECTS

To provide a seal area measure vision system in order provide sealing dies degrading monitoring and maintenance prediction or alert to change or clean the sealing dies before the seal get affected.

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