Faculty of Manufacturing Engineering

GLOVES HOLES DEFECT EVALUATION BY USING ELECTRONIC AIR LEAK TESTING MACHINE

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GLOVES HOLES DEFECT EVALUATION BY USING ELECTRONIC AIR LEAK TESTING MACHINE

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A thesis submitted in fulfillment of the requirements for the degree of Master of Manufacturing Engineering (Manufacturing System Engineering)

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DECLARATION

I declare that this thesis entitle "Gloves Holes Defect evaluation by using electronic air leak testing machine" is the result of my own research except as cited in the references. This thesis has not been accepted for any degree and is not concurrently submitted in candidature of any other degree.

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APPROVAL

I hereby declare that I have read this thesis and in my opinion this thesis is sufficient in terms of scope and quality for the award of Master of Manufacturing Engineering (Manufacturing System Engineering).

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DEDICATION

To my beloved wife, children, family, colleagues and friends.

ABSTRACT

Process variation in gloves manufacturing is one of major problem which is deviating the levels of quality. It is becoming more challenging than before especially in the medical gloves manufacturing area. The demand for a higher quality gloves product is getting tougher to meet and new technology to fulfill the demand is needed to meet the extended requirement. The method of confirming gloves product quality through sampling and AQL levels is getting more costly as it could lead to false sampling which extended to severe customer complaint and disastrous product recall. A higher technology with 100% product inspection is essential to ensure the gloves produced is 100% free from defects. The purpose of this research is to provide a better assurance of product before shipped to customer by eliminating the sampling size method and replace it with a 100% inspection method. A machine was developed by a machine manufacturer which is called Leak Test Machine to sort out defected gloves with pin holes. Initially, method used to sort out defect and good gloves from a container ($\pm$4000 pieces) is by using pressure to inflate the gloves, pressure differential of initial test value compared to finished test value will be counted through designated time given. A set point which sets as a border line between defect value and accepts value is determined by operator through series of validation but due to the process variation, the properties of gloves will not be exact in term of tensile strength, elongation and thickness. This will lead to either rejecting good gloves or accepting defect gloves. To reduce the uncertainties of defect / accept gloves from those variations, a research to analyze the efficiencies of those two methods will be studied. It is expected that the Leak Test Machine with 100% inspection method, is capable of conducting the gloves pinhole test with the same capability or better than the Water Leak Test method by measurement and analysis through this research. Through the research performed, it is concluded that by using the Pneumatic Leak Test machine through 100% inspection, it is expected to screen out defect at 37 % better than the Water Leak Test through AQL sampling.

ABSTRAK

Perubahan proses dalam pembuatan sarung tangan adalah salah satu masalah utama yang mengganggu tahap kualiti. Ia menjadi lebih mencabar daripada sebelumnya, terutama dalam bidang perkilangan sarung tangan perubatan. Permintaan untuk produk sarung tangan berkualiti yang lebih tinggi menjadi semakin sukar dan teknologi baru untuk memenuhi permintaan yang diperlukan bagi memenuhi keperluan terbaru. Kaedah mengesahkan kualiti produk sarung tangan melalui sampel dan tahap AQL adalah semakin mahal kerana ia mungkin membawa kepada persampelan yang tidak tepat yang mungkin membawa kepada aduan pelanggan dan kemungkinan produk di panggil balik. Teknologi yang lebih tinggi dengan pemeriksaan 100 % adalah penting untuk memastikan sarung tangan yang dihasilkan adalah 100 % bebas dari kecacatan. Tujuan kajian ini adalah untuk memberi jaminan yang lebih baik kepada produk sebelum dipasarkan kepada pelanggan dengan menghapuskan kaedah persampelan dan menggantikannya dengan kaedah pemeriksaan 100 %. Sebuah mesin dengan kaedah 100 % pemeriksaan telah dibangunkan oleh pengeluar mesin yang dipanggil "Leak Test Machine" untuk mengasingkan kecacatan dari sarung tangan yang baik dan kecacatan lubang halus. Pada mulanya, kaedah pengasingan kecacatan sarung tangan dari satu bekas (± 4000 helai) adalah menggunakan angin untuk mengembungkan sarung tangan, perbezaan dari catatan tekanan awal dan tekanan akhir akan dibandingkan melalui satu masa yang ditetapkan. Satu tetapan sebagai garis sempadan antara produk yang cacat dan baik akan ditentukan oleh pengendali mesin melalui beberapa siri pengesahan tetapi kerana perubahan dalam proses berlaku, sifat-sifat sarung tangan tidak akan menjadi tepat dari segi kekuatan regangan, pemanjangan dan ketebalan. Ini akan membawa kepada sama ada membuang sarung tangan yang baik atau menerima sarung tangan yang cacat. Untuk mengurangkan ketidaktentuan sarung tangan cacat atau baik dari variasi tersebut, kajian untuk menganalisa kecekapan antara kedua-dua kaedah akan dikaji. Ia dijangkakan bahawa kaedah ujian menggunakan 100 % pemeriksaan mampu menyaring kecacatan lubang halus dengan keupayaan yang sama atau lebih baik daripada kaedah pemeriksaan menggunakan "Water Leak Test" melalui data-data pengukuran dan analisa melalui kajian. Melalui kajian yang dijalankan, kesimpulan bahawa dengan menggunakan mesin ujian kebocoran menggunakan Pneumatik melalui pemeriksaan 100 %, ia dijangka untuk menyaring kecacatan pada 37 % lebih baik daripada pensampelan 'Water Leak Test' melalui kaedah AQL.

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CHAPTER 1

INTRODUCTION

1.1 Background of study

In today's world, gloves industries have become more and more competitive. All organizations have to perform in order to survive and be profitable. As well as the rubber gloves manufacturing industry, the organization has to maintain the quality of its products to be able to satisfy customers and effectively compete in the market. In general, one of the most important concerns for the rubber gloves manufacturing industry is the reduction of common quality defects such as holes in gloves or generally called pin hole. As a result from the quality defect produced, not only does an organization waste its main raw material resources such, Latex and time to re-manufacture the products, re-test and isolate but it also contributes to the loss of customers' satisfaction, trust and marketability (Ploytip, 2012).

A method of inspection being used in gloves industries is by applying the Acceptance Quality Level (AQL). Acceptance Quality level may be defined as statistical quality control technique, where a random sample is taken from a lot, and upon the results of the sample taken the lot will either be rejected or accepted. It also defined as an incentives (at the discretion of the responsible authority) to reduce the inspection costs (by means of a switch to reduced inspection) should consistently good quality be achieved (ISO2859-1 1999).

As a reflect from the sampling method quality inspection of AQL, there is a 100 % inspection which is theoretically will give a better and accurate product quality levels by isolating the right good products and defect products but there are disadvantages of 100 % inspection method which for mass volume production like gloves industries, producing millions of pairs in a day. The disadvantages is its relative expensive cost of inspection processes, handling of product can produce more defects and tedious process to ensure no under rejection (under kill) to customer or over rejection (over kill) of product which is not an option for manufacturer. But as a whole, the advantage could be main factor to mitigate any single rejection from supplying to customer.

This research will focus on gloves pin holes inspection which is currently being used in glove manufacturer, inspected by both 100 % inspection of using a pneumatic pressure - Leak Test machine detector and traditional inspection of AQL method of sampling using water to detect pin holes defect. This research will focus on the defect determination of pin holes by both method and compare their efficiency. According to FDA (2008), the Quality System regulation at 21 CFR 820.5 states that each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device manufactured. This system must meet the requirements of the Quality System regulation. US FDA is the most stringent body that control entrance of medical gloves to USA and been used as a benchmark of quality system adhered in the medical gloves manufacturer for quality perfection.

1.2 Problem Statement

Ideally, for mass production manufacturing environment which produce and process millions of product per day, an AQL method of product inspection is followed to eliminate the tedious process of having each part inspect on each process before shipped to customer. A good

sampling plan will also protect the producer in the sense that lots produced at permissible levels of quality will have a good chance to be accepted by the plan (Edward, 2009).

In order to maintain the customers demand for quality gloves produced, gloves industries had apply the AQL method to determine their quality level acceptance rate as an indicator of either producing good gloves from lots to be shipped or hold as defected products. According to Edward (2009)., the acceptance quality control system that was developed encompassed the concept of protecting the consumer from getting unacceptably defective material and encouraging the producer in the use of process quality control by varying the quality and severity of acceptance inspections in direct relation to the importance of the characteristics inspected and in inverse relation to the goodness of the quality level as indicated by those inspections.

Industries tend to use this method of sampling inspection due to their advantages over 100 % inspection which is less product handling as excessive handling will produce defects, less inspector to hire, cost of 100 % inspection is too costly, undergo tedious processes and longer time of testing as compared to sampling method.

Despite the advantages of AQL inspection, today customers demanding for more reliable product which is striving for 'zero defect'. A pin holes on a gloves will enable penetration of blood during surgery to the medical practitioner but through the AQL sampling, a number of defect is allowed and accepted as long as the number of defect is passing the AQL sampling. This will definitely reduce the marketable of product and could lead to disastrous product recall which ended as loss to company.

Current method of inspection is using Water Leak Test by which 1 litter of water is injected into the hanging gloves mandrel, in 2 minutes inspection time, any water leaked out

from the gloves is consider defected gloves. This inspection is time consuming and uses many inspectors to do the gloves slotting and inspection.

Therefore, in this research, to resolve the problem, a machine call Leak Tester machine will be installed to have a 100 % inspection for detecting the gloves pin holes. The machine works by means of pneumatic air injected inside the gloves, pressure decay different (in psi unit) between initial testing point to final testing point measured (in time) is taken and any value exceeded pre-determine value will be rejected.

This research will identify the efficiency of both inspection procedures reliability through DMAIC and identify which method is the best option for gloves pin holes detection.

1.3 Objective of Study

The objectives of this study are:

i) To determine the repeatability and reproducibility of Leak Test Machine to isolate holes defect.

ii) To compare the performance of Leak Test Machine with current method, water leak test.

1.4 Scope of the study

i) This study will investigate the gloves pin holes defect method of inspection between AQL sampling using water leak tester and 100 % inspection method using Leak Test machine.

ii) Any water leak tester and Leak Test machine will be used upon availability during the period of sampling.

This study will only apply to natural gloves product which the result will not be used for other gloves manufactured as the result may vary due to gloves chemical properties and composition.

1.5 Significant of study

This research conducted will bring great impact, as it could reduce or eliminate the number of customer complaint due to pin holes defect. A major turn from acceptance sampling method to 100 % inspection will ensure that product shipped to customer is guaranteed to be pin holes defect free and increase the marketability to current and new customers. The other advantage is reduction of number of inspectors to perform the inspection using Water Leak tester which will reduce cost of manpower.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

One of the most important concerns in the medical gloves industries is the pin holes which is a tiny hole that can never be traced with naked eyes. The pin hole raise a concern of integrity of the gloves as being a barrier protection to the user against direct contact to any un-known risk such as infectious decease. Glove integrity testing is therefore a main issue and has been addressed by many regulations such as those imposed by the USP, U.S. Food and Drug Administration, and Pharmaceutical Inspection Convention (Angela et. al., 2011). The concern about medical gloves being adequate barrier protection in the healthcare community has led to several studies investigating a possible virus penetration of gloves (Kotilainen et. al., 1992). The manufacture of sterile products is subjected to special requirements in order to minimize risks of microbiological contamination, and of particulate and pyrogen contamination. Much depends on the skill, training and attitudes of the personnel involved. (Annex 1 EU, 2008).

A test performed by Kotilainen et. al., (1992), to detect pinholes glove having potential of virus penetration. Hole was purposely punctured to the gloves with a 0.3 mm needles. A water leak test then performed to confirm the availability of the holes and its location and performed the virus penetration test after 2 minutes. It is found that there is virus penetration

happen on the leak area. Through this research, it is concluded that chances of having virus transfer through gloves pin hole is high for medical practitioner. By such definition, it is a top priority of medical device manufacturer which involve in the sterile glove product to explore the opportunities, ensure a good acceptable product is received by customer. The preference is to explore the possibilities through new technological knowledge, enhanced skills of employee through training and explore the un-tapped skills of workers.

In general, one of the most vital concerns for the rubber gloves manufacturing industry is the reduction of common quality defects such as holes and stain in gloves. From this point, not only does an organisation waste its resources and time to re-manufacture the products, but it also contributes to the loss of customers' satisfaction and trust (Ploytip et. al., 2012). The worst disastrous result of having bad product by customer is product recall or even termination of contract to supply. Testing of pin holes is inexpensive method but it is not a value added process which does not gives extra value to the gloves. A leaked glove which is with the appearance of pinhole will be life threatening for medical practitioner when dealing with contagious disease such as Ebola and Aids patient. To avoid the high risk of being infected, a double donning of gloves was introduced as a double protection from the risk during performing any medical procedure but there is still not a conformance to be free from infected. Double gloving is one of the measures used to protect surgeons from contamination by tissues and fluids when operating, however, few surgeons routinely wear double gloves, allegedly because of reduction of tactile sensation and manual dexterity. One way to encourage surgeons to wear double gloves is to make gloves more sensitive (Susan et. al., 1995). But it needs extra cost for R&D and new former mould to get an optimum surface roughness for the gripping purpose of small tools.

According to US Food and Drug Association (FDA 21 CFR 800.20), the prevalence of human immunodeficiency virus (HIV), which causes acquired immune deficiency syndrome

(AIDS), and its risk of transmission in the health care context, have caused the Food and Drug Administration (FDA) to look more closely at the quality control of barrier devices, such as surgeons' gloves and patient examination gloves (collectively known as medical gloves) to reduce the risk of transmission of HIV and other blood-borne infectious diseases. In order to overcome the risk of pinhole, method of testing had been designed to isolate and sorting the defect from pass through to customer. According to Angela et.al, (2011), there are 6 methods that have been explored for pinhole detection which are listed as below. The discussion will be detailed later.

1) Flow Test or air inflation test.
2) Water breakthrough or Water Leak Test.
3) Particle Penetration Test
4) Diffusional Test Ammonia
5) Visual inspection
6) Pressure drop test

Although method of testing the defect is established in standards, but 3 out of 6 test listed above is a destructive test by means, the tested gloves is considered defect after testing and cannot be commercialized to market. The most common method which is integrated in gloves industries today is the visual inspection and water leak test. To ensure consistent quality of glove manufacture, the Food and Drug Administration introduced a two-part testing protocol in which gloves are first inspected visually and then subjected to a water-leak test performed according to a national standard (Connell et. al., 2002). The other type of nondestructive test is pressure drop test through pressure decay comparison but it was not commercialized for mass production due to the effectiveness of instrument to accurately measure the pressure decay.

2.2 Acceptance Quality Level (AQL)

Medical practitioner such as doctors, nurses and operational room personnel is having the greatest impact of contact with patient's blood and body fluids. It is now a mandatory for all medical practitioners to take extra precautions during exposure to blood and body fluids avoiding blood borne decease. As a result, medical gloves were introduced to minimize the risk of transmission but breaches in gloves with pinhole may expose the operating room staff to the risk of infection particularly if there are cuts or abrasions on the skin. Breached gloves not only indicate the potential for infection via skin, but also bear witness to the possibility of having been a needle stick injury and thus potential inoculation of infected blood (Thomas et. al., 2000). The sampling inspection plan used by the FDA is derived from ISO-2859 (the International Organization for Standardization's) standard for "Sampling Procedures and Tables for Inspection by Attributes"), based on general inspection level II, normal inspection, and an acceptable quality level (AQL) of 1.5% for surgeons' gloves and 2.5% for patient examination gloves (FDA CFR 800.20). The reason of this stringent statement is nonetheless for the marketability and sustainability for gloves manufacturer.

Within the manufacturer community, the goal is to produce a zero defect product to be sustainable for their product marketing but maintaining the cost of producing at the lower cost as possible. Gloves manufacturer produce millions pair of gloves in a year, it is impossible to have all gloves produced to be inspected as it could cost a lot of investment for the quality control. According to Love et. al., (2005), there are 3 elements that make up a suitable definition of the total cost of quality.

1) Cost associated with conformance to standards.

   i) Appraisal cost.

   Cost of inspection procedures required to identify defective products.

ii) Prevention cost

Cost of prevention associated with methods, materials, design and training.

2) Cost associated with non-conformance.

i) Internal cost of failures which deals with scrap, rework and documentation before the product could be shipped.

ii) External cost of failures which deals with warranty cost, services and disastrous product recall. This cost associated with product failure after sales.

3) Derivative cost.

i) Cost which associated with holding of buffer stock, inventory and excess capacity as protection against quality uncertainties.

There are argument by which method of inspection should be followed to out weight the manufacturer profit needs and voice of customer (VOC). In the AQL model, management increases the cost of conformance (appraisal and prevention) such that non-conformance cost (internal and external failures) and derivative cost can be reduced. The net result is a reduction in total quality cost (Love et. al., 1995). As to compare with 100%, zero defect level, according to Love et. al., 1995, it is presumed that the cost for conformance (preventive and appraisal) raised but not so rapidly as to out weight the incremental gain in non-conformance failure cost, the net result is a total cost curves that has a minimum affect at the zero defect level. Gloves manufacturer had practicing the AQL sampling but since the demand for a better quality of gloves, exploring a better 100% inspection method which could mitigate, if success, supplying defect product to customers.