Surface Residual Process Improvement

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Abstract *— A manufacturing plant dedicated to the production of intraocular lens is observing a significant number of defects in their operations which has led to a decrease in the manufacturing yield. The project objective is to increase the yield and reduce the surface residual defect. Different techniques were applied to determine the root cause of the problem. The root cause was attributed to procedures not standardized and lack of materials. The actions implemented as part of this project were procedure standardization and purchase of materials. After actions were implemented, the surface residual reject rate was reduced by 1.35 % and the manufacturing yield was increased by a 1.5% meaning that the project objectives were accomplished.*

Key Terms *— Cataract, Intraocular Lenses, Process Improvement, Yield Increase*

INTRODUCTION

The Cataract disease is a clouding of the clear natural lens of the eye [1]. Cataract represent one of the mayor cause of vision loss in the world [2]. The most effective treatment for cataract is surgery. “Cataract surgery involves removing the clouded lens and replacing it with a clear artificial lens. The artificial lens, called an intraocular lens, is positioned in the same place as your natural lens. It remains a permanent part of your eye” [3]. “Cataract removal with Intraocular lens (IOL) implantation is one of the most frequently performed surgical procedures in current clinical practice. Modern cataract surgery is a refractive procedure and is performed to correct a refractive error such as myopia, hyperopia and astigmatism especially when associated to a decrease in accommodation” [4].

Problem Statement

A manufacturing plant located in Puerto Rico and dedicated to the manufacturing of intraocular lenses is observing a significant number of defects in their products. The defects observed during their manufacturing process has led the company to a decrease in the manufacturing yield. The current manufacturing yield is of 89%. The two major defects observed during the manufacturing process are surface residual with a 3.8 % of rejection and the optical fallout with a 2.2% of rejection.

The scope of the project was focused in reducing the surface residual defects. The optical fallout defects were out of the scope of this project. There are different categories of surface residual such as tray marks, water spots, tweezers marks, particles, and others. Figure 1 presents the different types of surface residuals observed during the manufacturing process and it show that the two major surface residual offenders are particles and tray marks.

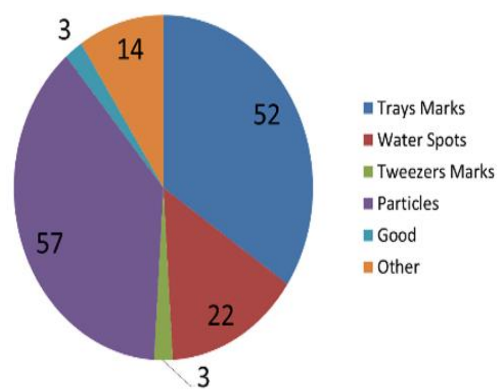

Figure 1
Pareto Diagram for Surface Residual Offenders

Objective

The objectives of this project is to reduce surface residual defects by at least 1% and to increase the inspection yield.

Background

The process to manufacture the intraocular lenses start with the acrylic preparation, then this acrylic is prepared and freeze to be cut and milled. During the cutting and milling process the intraocular lens is generated and its diopter power is given. After, the generation of the intraocular lenses, they are polished and cleaned. After cleaning stage, the lenses are submitted to a surface treatment process. The lenses are optically and visually inspected.

The visual inspection is performed by human operators and consists in the evaluation of cosmetic defects. During the inspection process, the operator may acquire eye fatigue condition due to the intense use of the eye during the visual inspection [3]. After the inspection process, the lenses are packed and sterilized.

ANALYSIS AND RESULTS

During the project different techniques were used to determine the root cause of the problem. Some of the techniques applied were the cause and effect diagram and the 5 Whys technique. The cause and effect diagram presented in Figure 2 shows that the major cause of the surface residual defects are methods and materials.

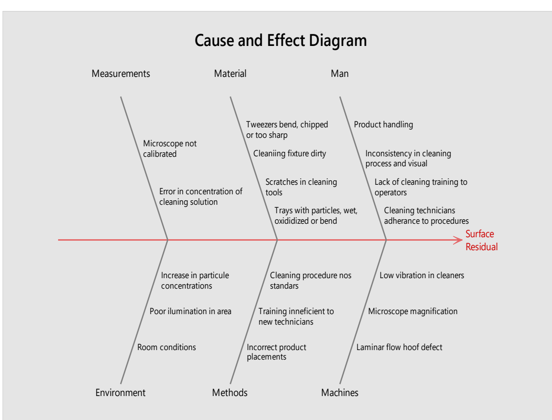

Figure 2

Cause and Effect Diagram

After the determination of the major causes for the surface residual defects, the manufacturing process for the unloading and cleaning operation were observed. The unloading and cleaning operation are the manufacturing steps where is most probable to occur the surface residual defect. From this activity it was noticed that the operators use different techniques to perform the manufacturing steps. The 5 Whys technique was used to identify the root cause of the inconstancy in the manufacturing process. From the 5 Whys technique presented in Figure 3 it was determined that there is no standard method defined for the unloading and cleaning operations.

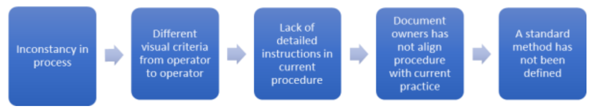

Figure 3

5 Whys

Surface residual defect and yield percent data were collected and analyzed to understand the process behavior. From the process capability and control chart presented in Figures 4 to 7, it was observed that the process is in control but is not capable since the Cpk values are under 1.0.

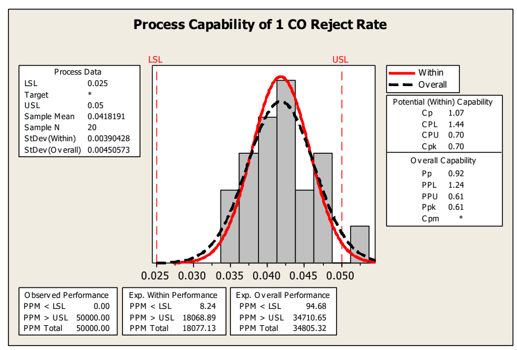

Figure 4

Surface Residuals Reject Rate Process Capability

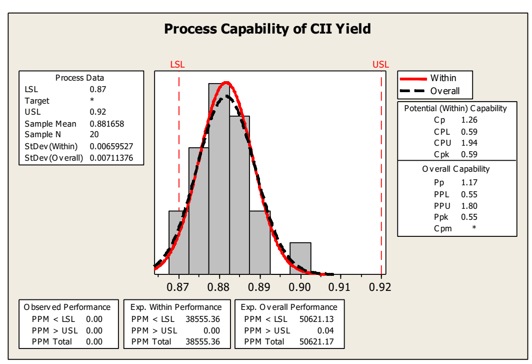

Figure 5

Yield Process Capability

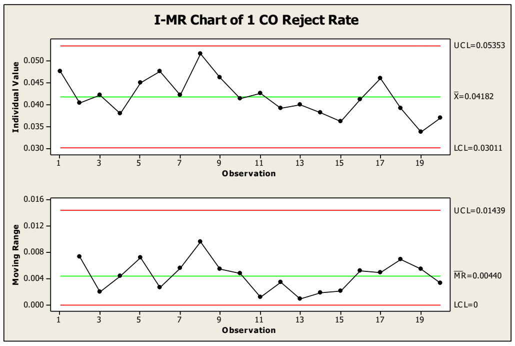

Figure 6
I-MR Chart for Surface Residual Reject Rate

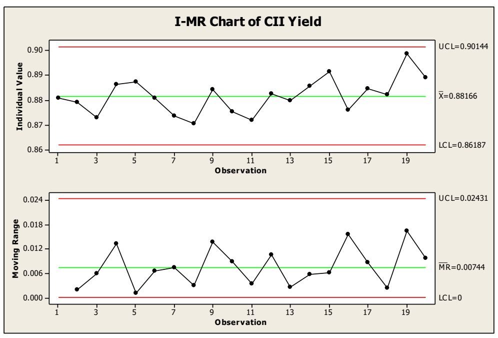

Figure 7
I-MR Chart for Yield Percent

DISCUSSION

As identified in previous section, the root cause for the increase in surface residual defects and the decrease in the manufacturing yield is due to the fact that there is no standard procedure defined for the unloading and cleaning operation. Therefore, a standard set of instruction was defined for the unloading and cleaning steps with the support of the stakeholders. After the instructions were standardized, the manufacturing procedure was modified to include step-by-step procedures, visual aids, critical points of actions and Do's and Don'ts for optimal results. Training in the updated manufacturing procedure were provided to the manufacturing operators and, after training completion, the procedures were implemented and release for manufacturing purposes.

After procedures implementation and release, the manufacturing process was monitored in a daily basis to identify if the procedures changes were being conducted and how the process standardization helped reduce the surface residual defect and increase the manufacturing yield.From the daily monitoring, data was collected and analyzed to understand the process behavior after the procedure's standardizations. Figure 8 presents that a Cpk value of 1.77 was obtained after procedure standardization and implementations demonstrating that Surface Residual Reject Rate was reduced. Figure 9 presents a Cpk value of 1.42 after procedure standardization and implementations demonstrating that the manufacturing yield was increased. Figure 10 present a reduction of 1.35% in surface residual reject rate after implementation of standard procedures. Figure 11 present an increase of 1.5% in Yield % after implementation of standard procedures.

In addition, from the analysis section was also concluded that beside method, material is another root cause for the increase in surface residual defects and the decrease in the manufacturing yield. To solve this, an order of instruments and supplies was placed to have the supplies and instruments available in the spare room.

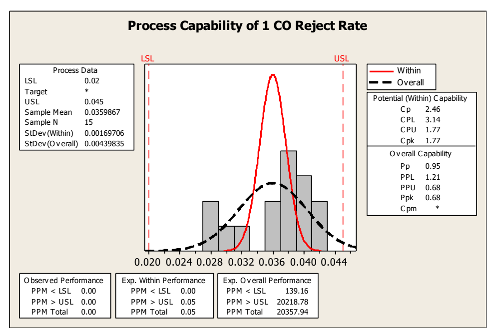

Figure 8
Surface Residuals Reject Rate Process Capability After Procedures standardization

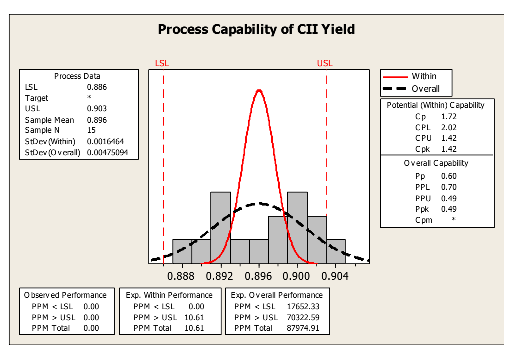

Figure 9
Yield Process Capability After Procedures standardization

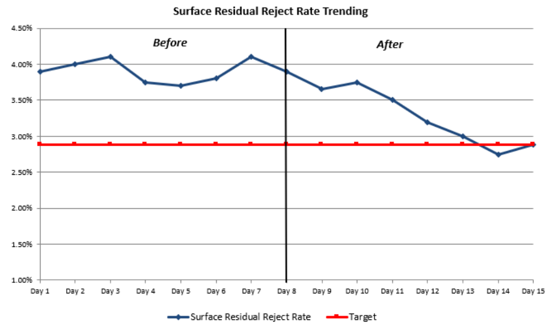

Figure 10
Surface Residuals Reject Rate Trending

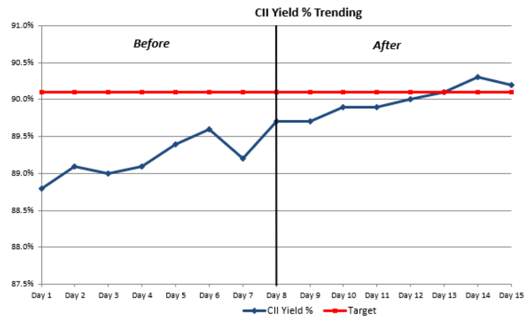

Figure 11
Yield % Trending

CONCLUSIONS

The actions implemented as part of this project provided successful results since the surface residual reject rate was reduced by 1.35 % and the manufacturing yield was increased by a 1.5% after the procedures implementation, meaning that the project objectives were accomplished. Internal audits will be conducted monthly to evaluate operator's performance. Also, periodic training sessions will be established for operators to maintain the control in process. Over time, financial assessments will be conducted to measure financial benefits due to reduced surface residual defects.

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