Center Thickness Optimization for Product A

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Graduate Project EXPO, February 2026

Abstract *— Every organization wants to increase its production and reduce the possibility of having scraps. Having to scrap products increases production costs, reduces cost savings, reduces volume output, and therefore reduces confidence in the manufacturing process. For a product to be released into the market, quality approval must be obtained. This quality approval considers compliance with critical to quality dimensions (CTQ) where no error or deviation must be found. Having a deviation on the CTQ triggers a Non-Conformance Investigation (NCR) that normally is resolved by scrapping the batch and product because there is nothing that can be done to fix it. Using DMAIC methodology, an investigation exercise will be conducted to understand the root cause of why this CTQ fails and how it can be solved and improved. Improving this CTQ will result in the reduction of NCR and make the manufacturing process more reliable, steady by reducing scrapped products and therefore increasing volume output.*

Keywords *— CAPA, Center Thickness, DMAIC Method, Tooling Design, SPC.*

PROBLEM STATEMENT

For this project, the focus will be on understanding and improving a critical to quality (CTQ) dimension for manufacturing product A. This CTQ is called "Center Thickness" and is a measurement taken during the quality inspection of product A. This CTQ must comply within a tolerance range, if a sample is found out of tolerance a Non-Conformance Report (NCR) is made and normally as a result the batch tends to be scrapped because the product cannot be saved. This therefore increases production costs, manufacturing yield reduces, volume released reduction and manufacturing behavior becomes unpredictable. With DMAIC methodology and tools, the reason why Center Thickness is found off will be understood and studied to find a solution to improve it. Improving the center thickness will make the behavior of the product CTQ dimension more stable, an NCR reduction regarding "Off Center Thickness" (Off CT) and reduction of batches scrapped due to Off CT.

PROJECT OBJECTIVES

The project objectives are to improve and centralize the Center Thickness behavior for product A. Through the improvement of the Center Thickness, a reduction of NCR regarding "Incorrect CT" resulting on a reduction of scrap costs, increased volume output, yield increase and cost saving.

PROJECT SCOPE

The project will seek to improve the Center Thickness for product A by developing an investigation exercise to identify the possible root cause of why the Center Thickness fails. After understanding and obtaining the root cause, improvement activities will be made to improve the behavior of the Center Thickness and a SPC (Statistical Process Control) analysis will be made to confirm if the improvement was significant.

LITERATURE REVIEW

In the manufacturing industry, to manufacture any product a series of steps must be made. To manufacture product A, a series of steps must be taken. First, a male plastic and female plastic mold is prepared using an injection molding process.

These plastic molds are formed by copying a tool design. This tool design contains the geometry and dimensions that are going to be passed to the plastic mold. After both molds are prepared, the male mold is placed inside the female mold. Between the male and plastic mold there is a separation gap. In figure 1, it can be appreciated the gap between the male and plastic mold.

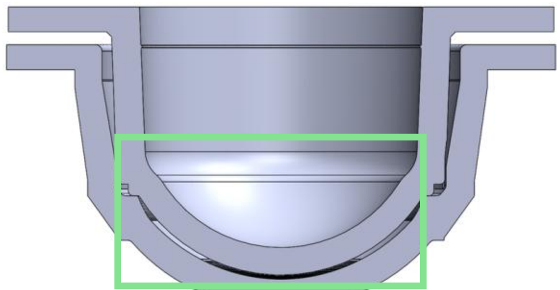

Figure 1
Representation of Male and Female Plastic Mold Merged with Gap

That separation gap is filled by a chemical that is product A material. After the product is filled, the material along with the molds are cured using an oven to harden the liquid and make the product copy the plastic properties (provided by the tool design). After being cured, a sample of molds are extracted and demolded (male and female mold are removed) to obtain product A. Product A critical dimensions are measured and verified following a quality sample criterion. If this criterion is approved and complies, the product passes on to the next process. For this first inspection, the gross part of the product that is located on the middle is verified and measured. This dimension is measured using a digital thickness gauge. The dimension obtained must fall between a specified range to comply with Quality Control and the product be able to pass to the next step. This dimension is called "Center Thickness" and if this dimension is found off, the product must be scrapped, adjustment must be made on the process, and the product is not released to the second stage until the first quality control is passed. The center thickness can be defined as the center point where product A is at its thinnest point according to [1]. This measurement is important because it dictates the behavior and performance for product A. Normally, the Center Thickness is associated for optical lens and if a Center Thickness is found out of specification it can affect the optical performance of the lens like focus, confort & reliability [2]. On figure 2, it can be appreciated a reference of the center thickness.

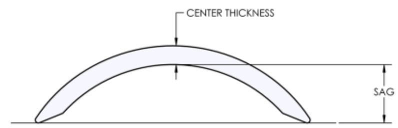

Figure 1
Center Thickness Reference.

If the product cannot be able to approve the first quality control even after adjusting, the product is entirely scrapped, and the product remains closed on the quality system. By staying closed on the quality system, the product cannot be released or passed to the next stage. If the product passes the first quality control, they pass through a second stage process. This second stage starts with the plastic molds passing through a separation process where the male mold is separated from the female mold, and the product stays with the female mold. Then, the product is removed from the female mold and transferred onto an automatic inspection camera to inspect any damage or impurity. After the product is inspected, if approved by the inspection system passes through an extraction and hydration process and then it is packed on a blister that is then sealed and transferred to a sterilization process which is subjected to a second and final quality inspection. As on the first quality inspection, a sample representative of the batch is taken to inspect quality dimensions. For example, Center Thickness is verified again on the second quality inspection since on the extraction and hydration process the product increases its center thickness due to the hydration process. The product increases its dimensions because on the hydration process, the product is humidified and absorbs a specified liquid that dictates the change of dimension. This change in dimension makes the Center Thickness grow a significant amount and that is why is verified again. As part of the second quality inspection, a quality sample is followed. If this quality sampling is approved for the Center Thickness, along with other critical dimensions, the product is released to the market. If not, an NCR is developed resulting in the scrap of the product and entire batch. The NCR opens an investigation that normally results in the scrap of the batch because it indicated the product was out of dimensions, and nothing could be done to fix it. For this project, since a significant number of NCRs have been obtained due to Off-Center Thickness, a Corrective Action & Preventive Action Activity (CAPA) was opened to investigate what we're causing the Center Thickness to go off.

METHODOLOGY

To understand how the "Center Thickness" can be improved, a methodology must be adopted. A DMAIC (Define, Measure, Analyze, Improve & Control) methodology will be used. This methodology will be applied because it has different tools that help in understanding what part of the process could be affecting the "Center Thickness" and what can be proposed to improve it. According to [3], DMAIC structure can be defined as a problem-solving methodology that focuses on solving complex problems that are happening for products or services. Since we have a complex problem, the DMAIC structure is a good criterion to utilize.

Define phase: For the define phase, the tool that was used was a Gantt Chart containing the activities going to be executed for this project. This Gantt chart will serve as a guide and reference to develop the project investigation and confirm what causes the Center Thickness to go off tolerance. In Table 1, the Gantt Chart used for reference can be appreciated. The timeline and execution of the activities will be based on the availability of the required resources and the testing time available.

Table 1
Gantt Chart Used for Reference

Task	Start	End
Define Stage	Week 1	Week 2
Project Assignment with Objectives & Resources	Week 1	Week 1
Project Charter including Business Case, Goal Statement, Scope & Timeline	Week 2	Week 2
Measure Stage	Week 2	Week 4
Data Collection Exercise	Week 2	Week 6
Statistical Analysis	Week 5	Week 5
Meeting with Product Designer	Week 6	Week 6
Analyze	Week 6	Week 9
Brainstorm Analysis	Week 6	Week 6
Engineering Testing Baseline	Week 7	Week 12
Improve	Week 12	Week 12
Tooling Iteration Design 1	Week 12	Week 14
Tooling Iteration Testing 1	Week 15	Week 18
Tooling Iteration Design 2	Week 19	Week 21
Tooling Iteration Testing 2	Week 22	Weeek 25
Tooling Iteration Design 3	Week 26	Week 28
Tooling Iteration Testing 3	Week 29	Week 31
Tooling Validation on Pilot Line	Week 33	Week 34
Control	Week 34	Week 52
Deployment of New Tool Design	Week 35	Week 52
Process Monitoring of New Tool Design	Week 35	Week 52

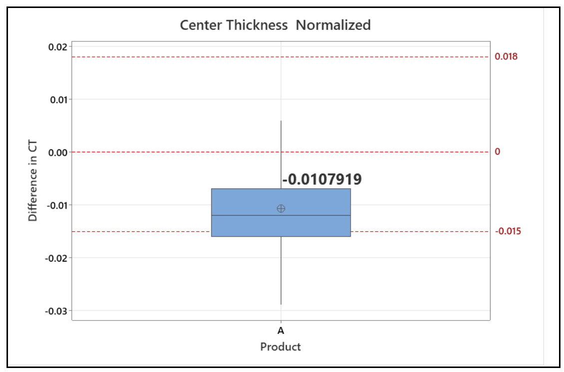

Figure 4
Center Thickness Behavior Normalized

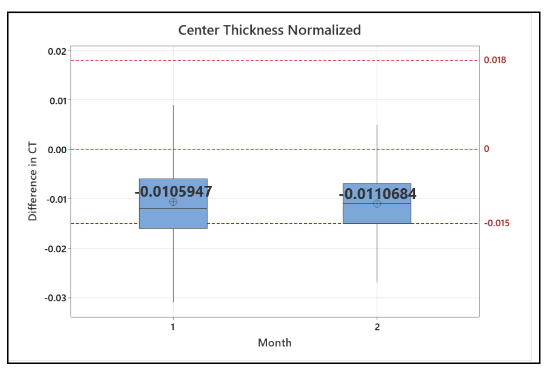

Figure 5
Center Thickness Behavior Normalized by Month

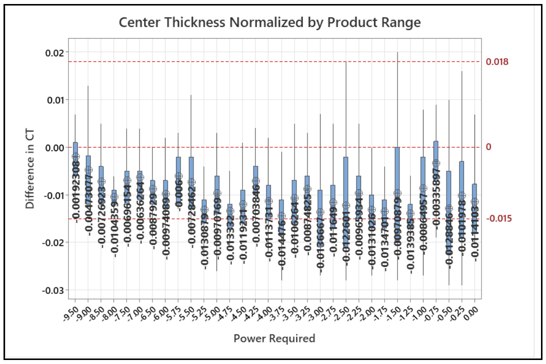

Figure 6
Center Thickness Normalized by Product Range

Measure phase: As part of the DMAIC structure, a measure stage was developed. For this phase, a data collection exercise was made by obtaining the current behavior of the Center Thickness for a period of two months. The information was obtained from the quality system database, where product A is sampled for quality control before it was released. To develop a uniform analysis, product A center thickness measurements were normalized to a specific range of -0.015mm to 0.018mm. The normalized measurements were considered because product A has different configurations and different tolerance values based on the product configuration. For example, the center thickness range for product A specification of -0.25 is 0.122mm up to 0.162mm, while for -3.25 the range is 0.071mm to 0.107mm. In Figures 4, 5, and 6, the normalized behavior of the Center Thickness for product A can be appreciated. On average, it can be appreciated that the current behavior for the center thickness is shifted downward for the entire product range and specifications.

A process capability analysis was made for the product range, where a central capability index ratio (cpk) of 0.19 was achieved. According to [4], a process capability analysis indicates to us what is the current capacity of the process. Obtaining a capability analysis shows us our current process capability and based on the result it can suggest improving the capability by developing a Lean Six Sigma project. In Figure 7, the process capability report can be appreciated.

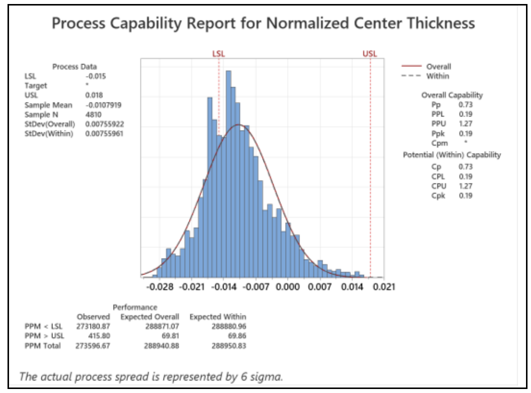

Figure 7
Center Thickness Process Capability

Based on this information, it can be confirmed that the Center Thickness currently is shifted toward the lower specification limits.

Analyze phase: From the data collection exercise, it was obtained that the performance of Center Thickness for product A is on the low specification. To understand what could be affecting the performance of the Center Thickness, a Brainstorming was made. Brainstorming was chosen because it is a method where a it can generate a quantity of ideas that can promote the root cause of an issue [5] and for determining what could be the reason of why the Center Thickness can be affected, brainstorming is a good tool. On Figure 8, the brainstorming exercise is developed.

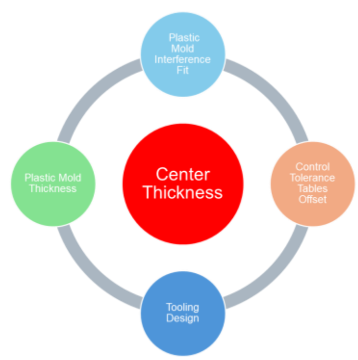

Figure 8
Brainstorming Exercise for Center Thickness

On the brainstorming analysis, 4 variables were considered that could affect the Center Thickness behavior. The first is the Plastic Mold Interference Fit, which can be considered as the resistance or the interference performed when the male and female molds are placed together. Currently, in the manufacturing process, there are over three available designs to adjust the interference fit and to be able to manufacture the product. Also, the design that provides the least interference fit has been known to influence adjusting the Center Thickness. But this creates a limitation in using only one interference fit design.

The second variable is Plastic Mold Thickness. The plastic mold thickness currently is a result of the tooling designs that create the geometry of the plastic mold. The plastic thickness is adjusted to a specific value during the manufacturing process for the yield performance aspects. The plastic thickness can be a variable since the plastic molds are injection molded; due to how the plastic mold cools down and shrinks, it could influence the plastic thickness.

The third variable is tooling design. Tooling design is the actual design used to manufacture product A and its specifications. Tooling design oversees the interference fit designs and the plastic molds' behavior and geometry. The fourth variable considered is the Control Tolerance Tables. The control tolerance tables are the range values used for the Quality Control System to determine if the Center Thickness is within specification or not. To confirm the brainstorming analysis, a reunion with a product designer was scheduled and he suggested to develop a test to confirm if the tooling design was off or the control tolerance tables are off. He ruled out the other two variables, because from his experience and knowledge determining the opportunity for the Center Thickness will lie on the Control Tolerance Tables or the Tooling Design.

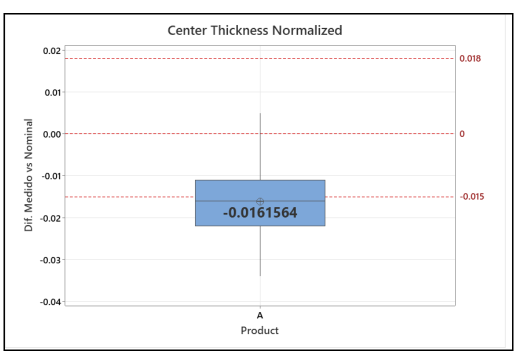

Figure 9
Normalized Center Thickness

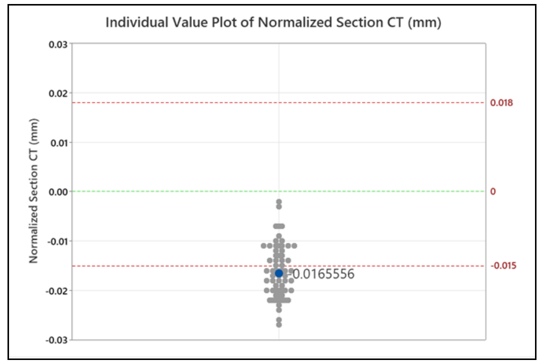

Figure 10
Normalized Cross-Sectional Center Thickness

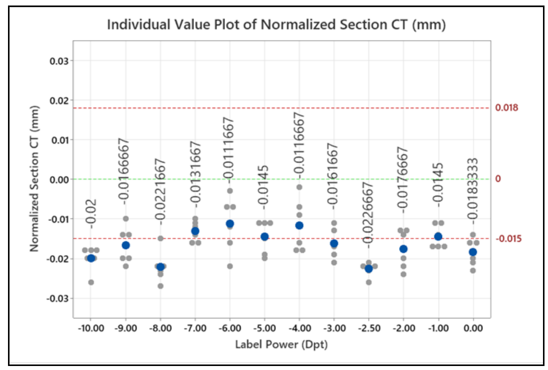

Figure 11
Normalized Cross-Sectional Center Thickness by Product Range

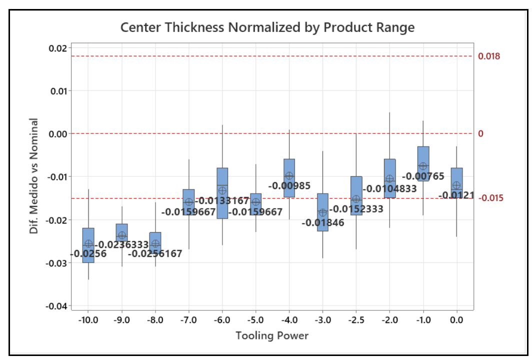

Figure 12
Normalized Center Thickness by Product Range

To confirm this, a test run was performed where the Center Thickness was measured following the actual Control Tolerance Tables and some samples were taken to be cross sectioned to confirm from a design aspect if the Center Thickness was off from design. A comparison of the behavior from the Measured and Cross Sectioned samples was obtained and the behavior was similar. This rules out the option of the Control

Tolerance Tables and leaves that the Tooling Design has opportunities and a redesign must be done. On Figure 9 it can be appreciated the Center Thickness measurement from the test normalized to the Control Tolerance tables and on Figure 10 it can be appreciated the Cross-Sectional Measurement normalized. In Figures 11 and 12, the normalized Cross-sectional and Measurement of the Center Thickness by product range can be appreciated. From the figures, it can be confirmed that the tooling design has an opportunity and needs to be redesigned.

Improve phase: As confirmed from the brainstorming exercise and testing from the measurement phase, a tooling redesign was needed. For this case, a collaboration was made with a Product Designer to help us design a new tool design that could centralize and improve the Center Thickness. To improve the Center Thickness, the product designer had to develop adjustments to the design, manufacture the testing tooling so we could manufacture the product, test it and confirm if the design worked. This process is known as an iteration. For this project over 3 different iterations were developed until the third iteration gave the results wanted. The third iteration resulted on an increase and more centralized Center Thickness for measurements and cross-sectional measurements. From figures 13 to 16 it can be appreciated the more centralized and increase of Center Thickness behavior for both measured and cross sectional. This iteration resulted as the go design for implementation. after the cycle.

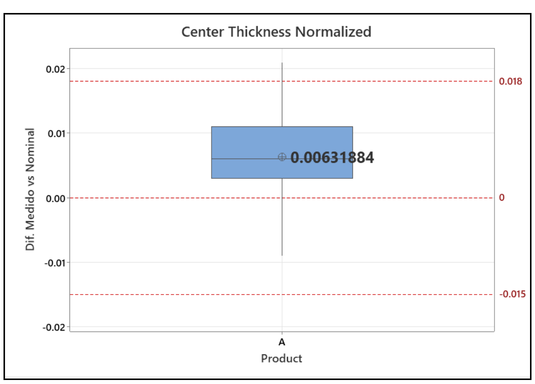

Figure13
Center Thickness Normalized for Third Iteration

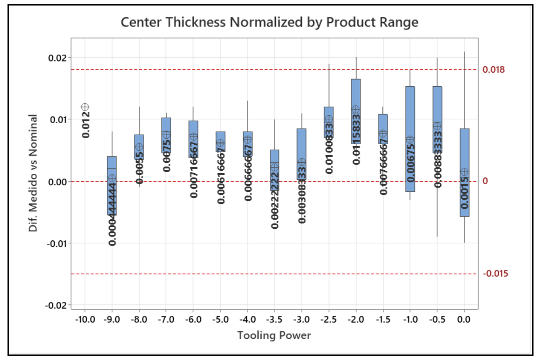

Figure 14
Center Thickness Normalized by Product Range for Third Iteration

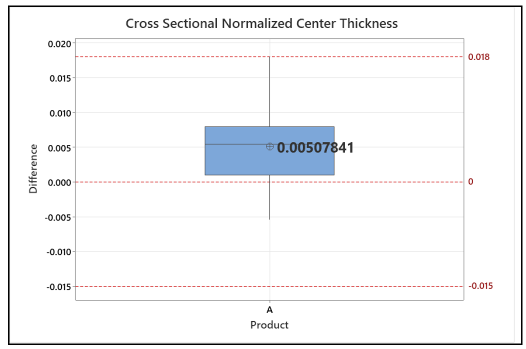

Figure 15
Cross-sectional Center Thickness Normalized for Third Iteration

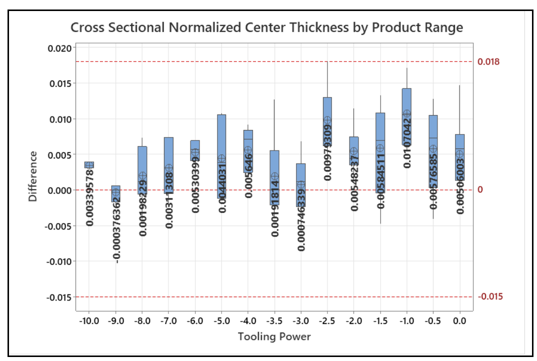

Figure 16
Cross Sectional Center Thickness Normalized for Third Iteration

After confirming this was the tooling design to implement, an Engineering Change Order was developed. This Engineering Change Order requested to develop a Performance Qualification of two consecutive lots to confirm that the Center Thickness behavior resulted equally or similar as on the iteration testing. This Performance Qualification resulted in a validation protocol that needed to be executed and passed before having the go to implement the new tooling design. This performance qualification was developed on a production batch considering normal operations such as change in materials, work shifts and production requirements to confirm if the design will comply with the manufacturing variability. The executed validation protocol resulted in a pass with zero deviations and non-conformities and most important, with the Center Thickness improved. The results of the performance qualification can be appreciated through figures 17 to 18. On the figures it can be appreciated an increase in the Center Thickness behavior indicating the new tooling design performed its intention. A statistical ANOVA analysis was performed to confirm if the new tooling design represented and statistical change and resulted in a yes. A p-value of 0.000 was obtained indicating that this new optical tool did increase and improve the Center Thickness.

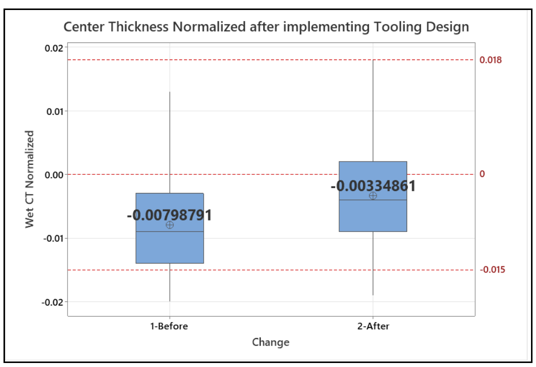

Figure 17
Center Thickness Normalized Behavior after New Tooling Design

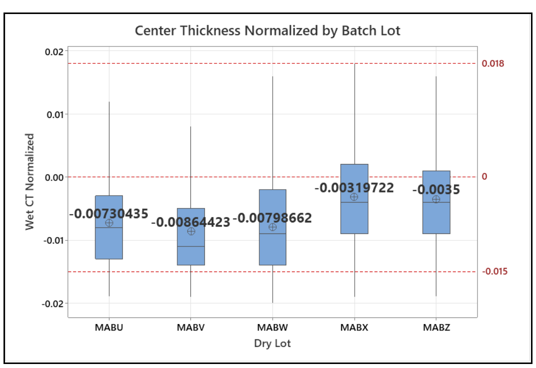

Figure 18
Center Thickness Normalized Behavior by Batch Lot After New Tooling Design

Control phase: In the improvement stage, it was confirmed and validated that the new tooling design. As the design was validated and approved, a deployment activity was carried out to implement the new tooling design on the manufacturing lines. The deployment activity is being carried out by the manufacturing business unit. As part of the monitoring controls, the Center Thickness is monitored for every batch lot, and if an off-center thickness is found, an NCR is generated and investigated. In Figures 19 and 20, the before and after changes for some of the manufacturing lines that have received the new tooling design can be appreciated. In Figure 21, it can be appreciated that the process capability report for the new tool design. A cpk of 0.46 was obtained. When compared to the cpk obtained from the data collection, it represents a change of 0.27 increase, therefore a 242% improvement. An ANOVA (Analysis of Variance) with hypothesis testing was made to confirm if the introduction of the new tool design represented a statistical change. Using the ANOVA analysis and considering a p-value of less than 0.05 to consider the implementation significant, a p-value of 0.00 was obtained. This indicates that statistically, the new tool design represented a change in the behavior of the Center Thickness. In Figures 22 and 23, it can be appreciated that the statistical analysis confirms the change in behavior for the Center Thickness.

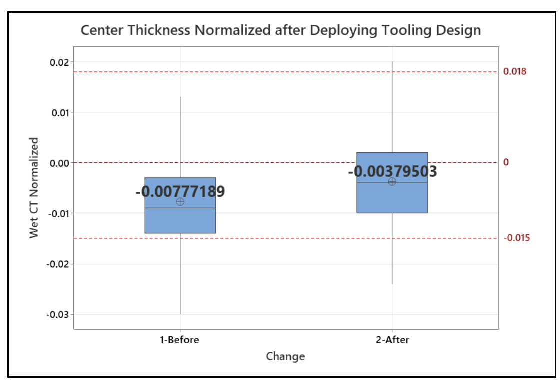

Figure 19
Center Thickness Normalized Behavior after New Tooling Design

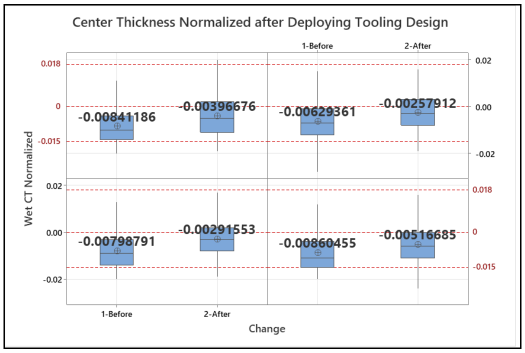

Figure 20
Center Thickness Normalized Behavior after New Tooling Design on Deployed Lines

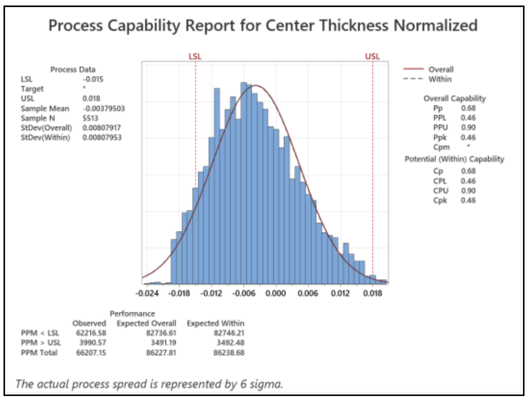

Figure 21
Process Capability for Center Thickness Normalized Behavior after New Tooling Design

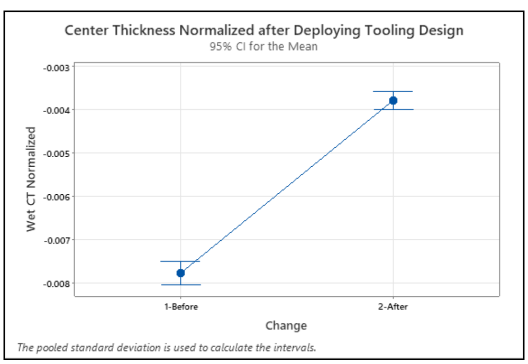

Figure 22
Center Thickness Normalized Behavior after New Tooling Design from ANOVA Exercise

Other benefits such as improving and centralizing the center thickness behavior are reduction on NCR from Incorrect Center Thickness, Yield Improvement, reduction of scrap product by NCR reduction, process stability and reduction in material consumption due to Off Center Thickness scrap. Also, the CAPA developed to investigate the off dimension was closed and resolved by the implementation of this new tool design.

Method

Null hypothesis	All means are equal
Alternative hypothesis	Not all means are equal
Significance level	α = 0.05

Equal variances were assumed for the analysis.

Factor Information

Factor	Levels	Values
Change	2	1-Before, 2-After

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Change	1	0.03314	0.033139	524.94	0.000
Error	8891	0.56128	0.000063		
Total	8892	0.59442			

Figure 23
ANOVA Exercise for Tool Design Deployment

Conclusion

For this project, a DMAIC methodology was applied to understand what could cause incorrect Center Thickness. Using brainstorming and data collection analysis, it was confirmed that the tooling design was off. This required redesigning, taking over three iterations resulting in a new and improved tool design. The new tool was validated and is currently being deployed on the manufacturing lines. Benefits of this project resulted in the improvement of the center thickness capability, centralization, and reduction of NCRs regarding incorrect Center Thickness, along with the support of CAPA (Corrective Action & Preventive Action) activities.

Acknowledgements

I would like to thank and extend gratitude to my mentor, Dr. José Morales Morales, for giving me the opportunity to be his student and for the guidance provided during this process. I also want to express my appreciation for those who collaborated with me during the development and execution of this project. hesitation. This collaboration led to accomplishment and achievement.

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