On-Time Delivery Improvement in an Injection Molding Process Applying a Problem-Solving Approach Based on Lean-Sigma and the MSA Effect

Mejora del índice de Entregas a Tiempo en un Proceso de Moldeo por Inyección de Plástico Utilizando un Enfoque Orientado a la Solución de Problemas Basado en Lean-Sigma y el Efecto del Sistema de Medición

Melhorar a Taxa de Entrega Pontual num Processo de Moldagem por Injeção de Plástico Utilizando uma Abordagem Orientada para o Problema Lean-Sigma e o Efeito do Sistema de Medição

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Summary. - Mexico's manufacturing industry is vital to the global economy. This industry has recently faced challenges due to the COVID-19 pandemic and globalized markets. Some developed countries can adopt innovative technologies; however, Mexico focuses on improving production processes with little investment, combined with existing resources and technology. Mexican companies use improvement techniques such as Six Sigma and Lean Manufacturing to achieve this goal. This study reports a method called Lean-Sigma that, unlike traditional methods that take months or even years to solve a problem, our method offers results in weeks, avoiding waste generation and speeding up decision-making. The proposed method consists of the following phases: identifying and measuring the problem, analyzing the root cause, developing a solution, and verifying the solution and control plan. The main characteristic of this approach is that it acts at the speed of Lean and uses engineering tools to solve problems and to demonstrate how the measurement system error could affect the achievement of the single-minute exchange of die (SMED). To validate the proposed method, a case study is presented in a plastic injection molding process in a manufacturing company located in Ciudad Juárez (Chihuahua, México), which has a late delivery rate that causes delays in the final assembly lines. Implementing the suggested strategy increased on-time deliveries from 77% to 99.36% in six weeks.

Keywords: Lean-Sigma, problem-solving, SMED, OTD, MSA.

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Resumen. - *La industria manufacturera de México es vital para la economía mundial. Esta industria ha enfrentado recientemente algunos retos debido a la pandemia COVID-19 y a la globalización de los mercados. Algunos países desarrollados pueden adoptar tecnologías innovadoras; sin embargo, en México, la atención se centra en la mejora de los procesos de producción con poca inversión, combinada con los recursos y la tecnología existentes. Las empresas mexicanas utilizan técnicas de mejora como Seis Sigma y Manufactura Esbelta para lograr este objetivo. Este estudio reporta un método denominado Lean-Sigma que, a diferencia de los métodos tradicionales que tardan meses o incluso años en resolver un problema, nuestro método ofrece resultados en semanas, evitando la generación de desperdicios y agilizando la toma de decisiones. El método propuesto consta de las siguientes fases: identificación y medición del problema, análisis de la causa raíz, desarrollo de una solución y verificación de la solución y del plan de control. La principal característica de este enfoque es que actúa a la velocidad de Lean y utiliza herramientas de ingeniería para resolver problemas, así como para demostrar cómo el error del sistema de medición podría afectar a la consecución del cambio de troquel en un minuto (SMED). Para validar el método propuesto, se presenta un caso de estudio en un proceso de moldeo por inyección de plástico en una empresa manufacturera ubicada en Ciudad Juárez (Chihuahua México), la cual tiene una tasa de entrega tardía que ocasiona retrasos en las líneas de ensamble final. La aplicación de la estrategia sugerida aumentó las entregas a tiempo del 77% al 99,36% en seis semanas.*

Palabras clave: *Lean-Sigma, Solución de Problemas, SMED, Entregas a Tiempo, MSA.*

Resumo. - *A indústria transformadora do México é vital para a economia global. Esta indústria tem enfrentado recentemente alguns desafios devido à pandemia da COVID-19 e aos mercados globalizados. Alguns países desenvolvidos podem adotar tecnologias inovadoras; no entanto, no México, a tónica é colocada na melhoria dos processos de produção com pouco investimento, combinada com os recursos e a tecnologia existentes. As empresas mexicanas utilizam técnicas de melhoria como o Six Sigma e o Lean Manufacturing para atingir este objetivo. Este estudo relata um método chamado Lean-Sigma que, ao contrário dos métodos tradicionais que levam meses ou mesmo anos para resolver um problema, o nosso método oferece resultados em semanas, evitando a geração de resíduos e acelerando a tomada de decisões. O método proposto consiste nas seguintes fases: identificação e medição do problema, análise da causa raiz, desenvolvimento de uma solução e verificação da solução e do plano de controlo. A principal caraterística desta abordagem é que actua à velocidade do Lean e utiliza ferramentas de engenharia para resolver problemas, bem como para demonstrar de que forma o erro do sistema de medição pode afetar a realização da troca de moldes num minuto (SMED). Para validar o método proposto, é apresentado um estudo de caso num processo de moldagem por injeção de plástico numa empresa de produção localizada em Ciudad Juárez (Chihuahua, México), que tem uma taxa de entrega tardia que causa atrasos nas linhas de montagem finais. A implementação da estratégia sugerida aumentou a pontualidade das entregas de 77% para 99,36% em seis semanas.*

Palavras-chave: *Lean-Sigma, Resolução de problemas, SMED, Entrega atempada, MSA.*

1. Introduction. - The On-time delivery is a challenge faced by manufacturing companies today, negatively impacting product quality, customer satisfaction, and overall organizational efficiency [1]. According to Kholil et al. [2], the internal factors make this a difficult challenge to solve, including internal process capabilities, maintenance strategies, and supply chain coordination. However, external factors, such as the COVID-19 pandemic, have also caused the closure of raw material manufacturing companies worldwide, delaying supply and reducing the time required for transformation into finished products [3][4].

Horzela & Semrau [5] stated that one of the factors that contribute negatively to on-time delivery is the machine availability, which is a critical factor in ensuring on-time delivery in the manufacturing industry. Trakulsunti et al. [6] stated that by maintaining high levels of machine availability, minimizing downtime, and effectively managing production schedules, manufacturers can improve their ability to meet customer demands, fulfill delivery commitments and remain competitive. To achieve increased machine availability, companies must work on becoming more flexible and with little economic investment; therefore, they use continuous improvement (CI) approaches [7], [8], which play a crucial role in organizations [9].

Furthermore, CI initiatives, such as Total Quality Management, Lean Manufacturing (LM), and Six Sigma (SS), are critical in achieving flexibility [10]. These initiatives emphasize the importance of process improvement, employee training, and flexible production processes as key elements [11]. The benefits of such CI programs are that they enable organizations to adapt to changing and uncertain environments, stabilizing performance on the one hand and improving adaptability to change on the other [12]. This adaptability is critical for organizations to remain flexible in dynamic market conditions [13][14].

To improve flexibility and operate in a more stable state, responding to changing market demands and conditions, companies use approaches such as Lean Six Sigma (LSS) and Lean-Sigma (LS) [15]. The LSS approach is a process improvement methodology that combines the principles of Lean Manufacturing and Six Sigma [16]. This is because by integrating Lean's focus on waste reduction and value creation with the data-driven analytical tools and problem-solving methodologies of Six Sigma, organizations improve process performance, efficiency, and customer satisfaction [17]. On the other hand, LS differs in the problem-solving-oriented approach, which provides results in a short period, unlike LSS, which is more oriented to CI projects that can take, on average, 12 months to obtain results and determine if decisions have been correct [18].

In Mexico, using these continuous improvement tools is of great importance as it is a country with a developed manufacturing sector that contributes to the national economy. For example, by 2023, there were 579,828 companies in the manufacturing sector in the country, of which 486 were in the state of Chihuahua and 330 in Ciudad Juarez, representing 70% of the total in the entire state. These companies generate approximately 3 million jobs nationwide, 500,000 in Chihuahua state and more than 300,000 in Ciudad Juarez. This means that 60% of jobs in this sector in the state are generated in Ciudad Juarez, representing 11% at the national level [19]. Therefore, it is important to examine the industrial sector.

Currently, some publications demonstrate how these CI tools are used and the advantages they provide to the organization, such as Estrada-Orantes et al. [16] show an application of the LS approach in a manufacturing company dedicated to the production of plastic components by injection, where one of the machines that made up the process experienced difficulties in meeting on-time deliveries with a highly demanded product Initially, 99% of the product had burs (excess material) on one side, and an operator was removed manually, representing a rework; thus, the process's Cpk index was -1.64, out of the specification limits. The LS approach solves the problem using process mapping, root cause analysis, brainstorming, five whys, design of experiments (DOE), and Kaizen.

On the other hand, Gracia & Moctezuma [17] present another application of LS in a gear and chain assembly process; the process had problems with on-time deliveries due to the addition of a new model, and a daily shipment sequence was required, gaining greater flexibility. Initially, the process had an on-time delivery rate of 66%, and by applying the LS, a work team was integrated to solve the problem. Using LM tools, the production line was balanced using takt time calculation and just in time (JIT) to increase productivity from 1.8 to 2.5 pieces/min*man, which positively impacted the manufacturing lead time from 26.07 to 17 seconds, equivalent to a 35% improvement. Consequently, the percentage of on-time deliveries increased from 66% to 100%, and the sequence of shipments complied with. This approach solved the problem within four weeks, and the process capability increased from 2.6 to 3.4 sigmas.

Condé et al. [20] show an LSS approach through the Define, Measure, Analyze, Improve, Control (DMAIC) methodology, employing a design of experiments to reduce defects in an automotive company. First, the main defects and factors that result in nonconforming parts in the casting and machining processes are identified. The design of experiments allowed for an increase in the quality level from 3.4 to 4 sigma's, which is an acceptable sustainable level. This indicates that LSS increases the quality levels of the process. However, it is necessary to wait six months to see the results, which generates the company incurring poor quality costs during that time.

Based on the previously mentioned applications, it is concluded that traditional continuous improvement approaches such as LSS and SS provide good results to organizations with efficiency, delivery, quality, and cost problems; however, the time required to provide acceptable results averages between six and 12 months, which has a negative impact on the costs and performance metrics of the organization. Furthermore, while the improvements achieved are acceptable, the original philosophy of these approaches, which is to bring processes to Six Sigma levels, has not been achieved. This approach stands out for LS and presents a more attractive form for companies because of its reaction time. It acts at the speed of lean, identifies the causes of problems, and resolves them in weeks, preventing companies from continuing to generate waste.

Therefore, this study aims to present the application of Lean Sigma in a manufacturing process with a problem-solving approach using industrial engineering principles. The novelty of this study is that results can be obtained in weeks, but it also shows that the error percentage of the measurement system could result in a milestone in achieving SMED. By solving the problem quickly, manufacturing companies can be flexible and cope with external factors, such as changes in demand, by improving on-time delivery rates and increasing customer satisfaction.

This case study was conducted in a company that manufactures gasoline pumps in the automotive sector. The demand for the plastic injection molding process fluctuated, and the number of parts delivered to the final assembly process was insufficient. This caused line stoppages and delayed deliveries to customers. The process of interest had 20 plastic injection molding machines, where the noncompliance rate ranged between 20% and 30%, resulting in late deliveries and high costs owing to low machine availability.

After this introduction, section two includes the methodology for this research. Section three discusses the results, section four reports the conclusions, and section five presents some of the limitations and future research.

2. Methodology. - The methodology used in this research is based on the DMAIC cycle and the Lean-Sigma approach, which consists of 5 stages, as shown in Figure I, which includes the steps and engineering tools used.

2.1 Step 1: Identify and measure the problem. - This step aims to define and delimit the problem and obtain initial data from the production process under initial conditions to determine the condition of the problem in terms of process capability. It starts with the formation of a multidisciplinary team dedicated full-time to the problem under analysis so that personnel from different departments can contribute ideas from different perspectives. Including the production supervisor, process engineer, manufacturing engineer, quality engineer, planning, and, if possible, at least two operators who perform the operation function are recommended. Once the work team is formed, it meets to identify and delimit the problem, using elements of a Project charter and defining the fundamental aspects, which include the Macro problem statement, project objective, project scope and limits, response variable, conditions, magnitude, performance, period, and specifications. This allows us to have a clear vision of the problem and to obtain important data, mainly to define the response variable that needs to be improved.

Subsequently, the work team collected initial data on the identified response variable. The data collection consists of obtaining the reports of the last weeks, where the value or performance of the response variable can be visualized, and tests are performed to confirm the normality of the data. If they are not normal, it is necessary to determine the type of distribution they follow for better analysis. Next, a control chart is created for individual data using Minitab software to analyze the trends and behavior of the response variable; however, the work team continues to monitor it to see trends and relate the out-of-control points with special events that occur in a specific period. Subsequently, a capability analysis is performed using the previously collected data and the specification limits to determine the parts per million defects and observe the size of the problem.

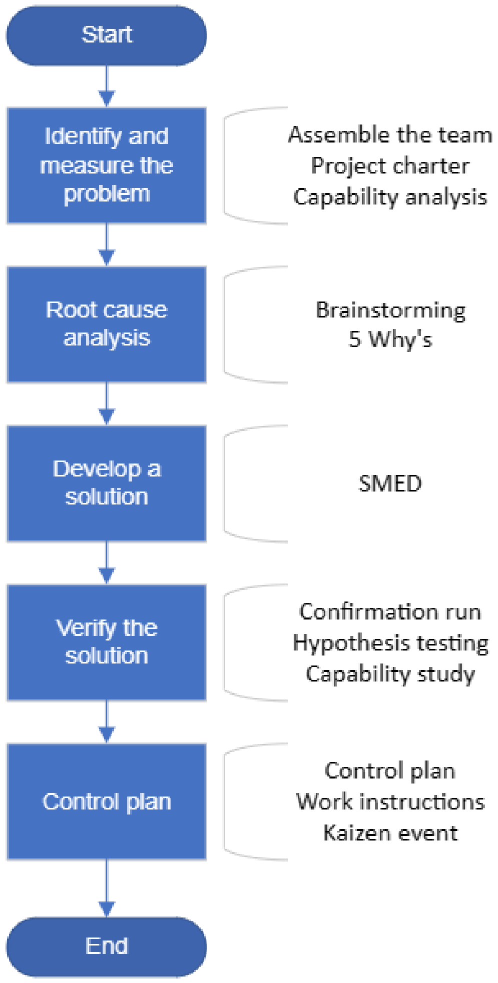

Figure I.- Flowchart of the proposed methodology based on the Lean-Sigma approach [16].

2.2 Step 2: Root cause analysis. - Once the problem is identified and the magnitude of the problem is determined, the team finds the potential causes that are generating the problem. First, the team engaged in brainstorming, where each participant brainstormed why the problem occurred, and the round continued until the ideas were exhausted. The moderator then refined the ideas to eliminate repeated ideas. With the list of ideas reduced, the nominal group technique was used to weigh ideas for each participant. Once the ideas have been weighed, the sum of the ideas is obtained, and the idea with the highest score is chosen. Finally, the 5 whys technique is applied, which consists of asking five times why the problem occurs, and the technique is stopped once a cause is found that does not point to a person or a department but is a cause that is under the control of the team and can provide a solution.

2.3 Step 3: Develop a solution. - Once the root cause is identified, a lean manufacturing or Six Sigma tool is used to solve the problem. In this case, the selected tool was SMED, which reduced the model to less than ten minutes. SMED is a Lean Manufacturing tool that reduces model changeover or setup times. This tool follows a well-structured methodology consisting of four phases, as Figure II illustrates.

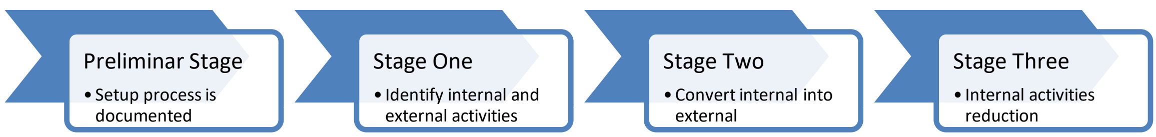

Figure II.- Stages for the SMED Technique.

The purpose of the preliminary stage is to document the activities involved in the model change, which is performed by mapping the process. It is recommended that a video of the process be captured to perform a detailed analysis, where the activities and times are recorded. Once the activities are identified and listed, the next step is to classify them into two categories based on their current performance and not on how they should be or are believed to be. This classification is based on both internal and external activities.

The external activity is performed while the equipment is still operating or has not finished producing the previous model. In contrast, internal activity is necessary when the equipment is stopped. Subsequently, in step two, the activities that can be eliminated because they are considered unnecessary or wasteful are identified, and the internal activities that can be carried out externally are listed. In this step, checklists can be developed to validate that external activities have been completed before the machine is stopped. Finally, in stage three, an action plan is made to work on process improvements that require investment to reduce the time of internal activities, some of which can be to perform activities simultaneously, purchase more tools, design and implement fixtures, and poka yokes, among others.

Once the SMED technique was implemented, the team monitored the duration of the model changeover time. It makes a control chart comparing before and after to determine if there is a significant reduction.

2.4 Step 4: Verify the solution. - This step is of great importance because it validates that the tool implemented in the previous step is practical for the response variable. After improvements were made, data were collected on the response variable, and a 2-sample T statistical test was performed at a 95% confidence level.

2.5 Control plan. - Finally, in this step, we carry out Kaizen events to train personnel in the new tool implemented in step three. In addition, work instructions, procedures, standards, and process control plans are modified as applicable.

3. Results and Discussion. - This section is divided into sections based on the information reported.
3.1. Identifying and measuring the problem. The following information was obtained during the team meeting, during which important aspects of the problem were defined.

- Macro Problem Statement: The production schedule in the molding area is not followed. On average, 30% of the time, the program is not completed on time, resulting in delayed delivery to the internal customer.
- Project Goal: To reduce schedule noncompliance from 30% to 15%.
- Project scope and limits: The project was conducted in a plastic injection molding area.
- Response variable: Y=Compliance with production schedule. A defect occurs when scheduled production is not 100%.
- Conditions: Defects occur on different days of the week and in different months. Magnitude: The cost of non-compliance with the production program in March 2024 amounts to $31,000, and a projection shows that the annual cost amounts to $372,000.
- Performance: The measurement scale was equivalent to the % of compliance with the program.
- Period: It was estimated that defects generally occur when downtime is triggered.
- Specifications: Compliance with the program should exceed 99.2%.

It is important to note that the company's goal of achieving an on-time delivery rate above 99.2% was unmet, and the annual loss was $372,000.

Next, the work team collected information on the on-time delivery rate using six months of production reports. A total of 120 data points were plotted weekly, resulting in 24 subgroups. The data was then subjected to a normality test, as shown in Figure III. A p-value above 0.100 indicated that the data was normal.

Figure III.- Normality test of the initial data for compliance with the production program.

Once the normality of the data was confirmed, a control chart was created to observe the behavior of compliance with the production program to observe trends, as shown in Figure IV, where the on-time delivery rate was within statistical control and exhibited normal behavior. It can also be seen that, on average, the compliance rate was 77.42%, with behavior ranging from 63.89% to 90.95%. With this data, in the worst-case scenario, the molding process delivered 37% fewer parts required by the following process, affecting the final assembly lines.

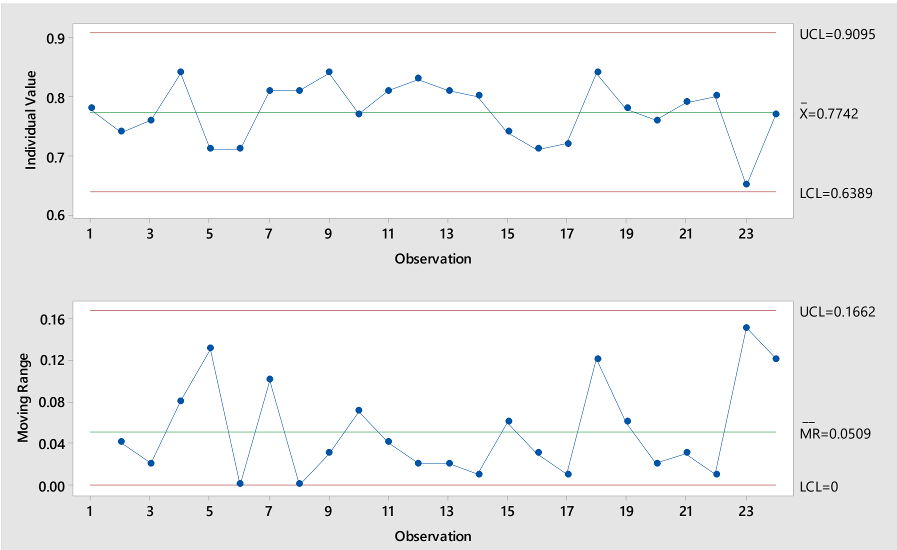

Figure IV.- Control chart of initial data regarding compliance with the production program.

Based on the company's goal of 99.2% compliance, a capability study was conducted to determine the process's sigma level and existing defective parts per million (DPPM). Figure V shows the analysis from which the following can be concluded: the process's initial C_{pk} is -1.61, which means that 100% of the time, the level of compliance was outside the goal set by the company; therefore, the initial sigma level can be set equal to zero.

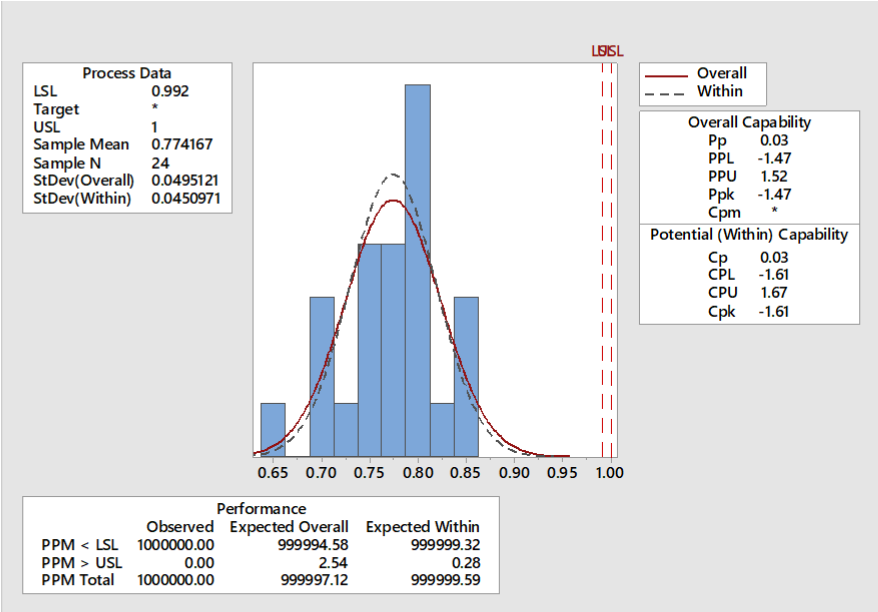

Figure V.- Process capability analysis performed on the OTD under initial conditions.

3.2. Root cause analysis. - Based on the information obtained and analyzed, basic quality tools were used to determine the root cause of the problem. First, the production area's multidisciplinary team, consisting of the production supervisor, group leader, maintenance technician, quality engineer, industrial engineer, tool crib technician and two equipment technicians, met to brainstorm ideas. Approximately 30 ideas were generated, some of which are listed in Table I.

No.	Idea
1	The machine does not achieve the production rate
2	Quality defects
3	Tool damaged
4	Training
5	Changeover time
6	Scheduling fluctuations
7	The production Schedule is not being followed
8	Missing materials
9	Failure in the dryers
10	Absenteeism

Table I.- Ideas generated by the multidisciplinary team

The team used the nominal group technique with a generated list of ideas, and each member assigned weights to the ideas. Table II shows the scores for each of the ideas, and it was found that the time required to change the model was the major contributor to not delivering on time.

No.	Idea	Score
1	The machine does not achieve the production rate	16
2	Quality defects	30
3	Tool damaged	1
4	Training	1
5	**Changeover time**	**40**
6	Scheduling fluctuations	28

7	The production Schedule is not being followed	19
8	Missing materials	0
9	Failure in the dryers	0
10	Absenteeism	0

Table II.- List of ideas with weights when applying the nominal group technique.

The team decided to focus primarily on problems with high model changeover times, which scored 40; therefore, it collected data on model changeover times in minutes in the production area. Figure VI presents the data collected for 280 events.

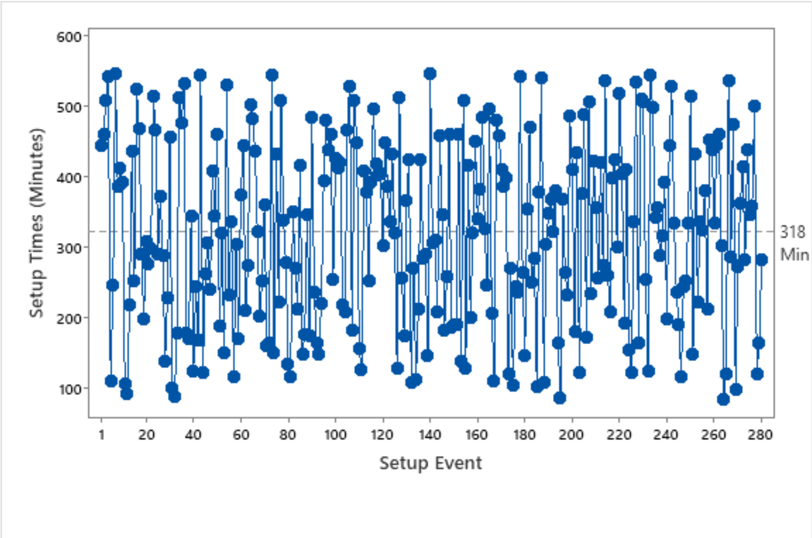

Figure VI. - Model changeover times under initial conditions.

The average changeover time was 318 min (~ 5 h). This indicates that more than half of the workday shift is lost when a model change is made, resulting in lower production and efficiency. Therefore, there is a correlation between high model change times and on-time deliveries owing to the loss of time available on the production line.

3.3. Develop a solution. - Once the root cause of the problem has been identified, the team discussed possible lean tools to counteract the adverse effects of model change over time. It identified the single-minute exchange of die (SMED) tool, a lean manufacturing tool that seeks to reduce setup and model changeover times to less than 10 min. Four phases of the SMED technique are described, and the results are shown below.

3.3.1. Identify model change activities. - The main purpose of this step is to identify the activities involved during a changeover; to do so, different model changes were analyzed. The changeover process was mapped to one of the machines, selecting one of the models that, according to the team's experience, generated the most problems, causing the setup time to increase up to 8 hours in the worst-case scenario. Once the process is mapped, the activities were identified and are listed in Table III.

No.	Activity Description	Time in Minutes
1	Go to the tool room to get the mold cavity and tools	13
2	Turn off heaters	3
3	Waiting to release a crane	35
4	Go to the tool room to get tools	15
5	Place holder and attach mold to the crane	4
6	Go to the tool room to get support to replace	17
7	Go to the tool room to get hoses	15
8	Disconnect hoses and clean	33

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9	Place locks on the mold	2
10	Take off eight supports	11
11	Open the clamp and disassemble the arrow	16
12	Take down the mold	3
13	Put in place next to the mold	6
14	Close clamps	3
15	Place supports on the mold (2)	6
16	Open the clamp and install the arrow	2
17	Install six supports to the mold	27
18	Take off holders to the crane and detach the mold.	1
19	Upload the program	2
20	Open the mold and adjust	4
21	Install 40 hoses	30
22	Go to the tool room to get a zip tie	16
23	Install the zip tie	6
24	Change the fixture to the robot	4
25	Adjust the water level	5
26	Review and fix the leakage	1
27	Go to the tool room to get resin to purge the machine	27
28	Preheat and purge	30
29	Make parts for setup validation	10
	Total Time in Minutes	347

Table III.- Documentation of changeover activities under initial conditions.

Some of the most relevant aspects to mention in this step are that, as shown in Table III, 29 activities can be identified in the model-change process. Similarly, it can be observed that the model changeover time is 347 min, equivalent to 5.78 hours, considering that the shift is 9 hours. This means that approximately 64.25% of the machine time is unavailable for production because of this increase in setup times, resulting in the company's current symptoms, that is, noncompliance with deliveries to the assembly lines.

3.3.2. Separate internal and external activities. - Once the process has been mapped and the activities involved have been identified, the work team classified each activity as internal or external. In this case, during the analysis, it was identified that all activities were performed internally, that is, while the equipment was stopped.

3.3.3. Convert internal activities into external. The team analyzed each activity in detail to convert those that can be performed externally before the equipment is stopped. Figure VII shows in the left graph that 24.1% of the activities can be performed externally, resulting in a ~39.8% reduction of the total changeover time, as shown in the right chart.

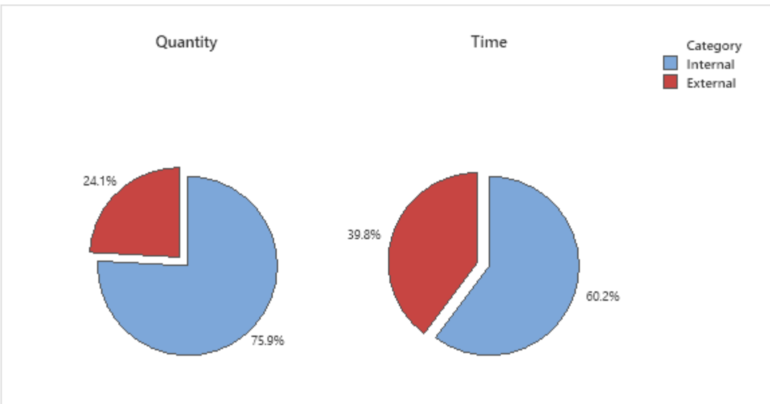

Figure VII.- Impact of converting internal into external in the total changeover time.

Using the fundamental principle of converting internal activities into external ones, the model changeover time for the analyzed setup was reduced from 347 to 209 min, which represents a decrease of approximately 40%. In addition, there were 7 external and 22 internal activities.

A setup preparation checklist was developed to list all necessary activities to achieve activity conversion. The tools must be available before the previous model's production ends. This ensures that when the machine stops, everything is available and within the reach of an efficient setup change. This step implemented a checklist and monitored the setup times to ensure that external activities were prepared before executing a model change.

3.3.4. Reduce internal activities. - Because the proportion of internal activities was still considerably high (76%), the team worked on reducing the time spent on internal activities in this phase. For this, the team proposed strategies such as developing fixtures, executing activities in parallel, and standardizing and documenting model change activities. Once these activities were implemented, the model change time was monitored for two weeks, collecting 25 data points, and a before vs. after graph was made.

As shown in Figure VIII, once the SMED technique was implemented, the model changeover times were reduced by approximately 73%, from 344.6 to 92.7 min on average.

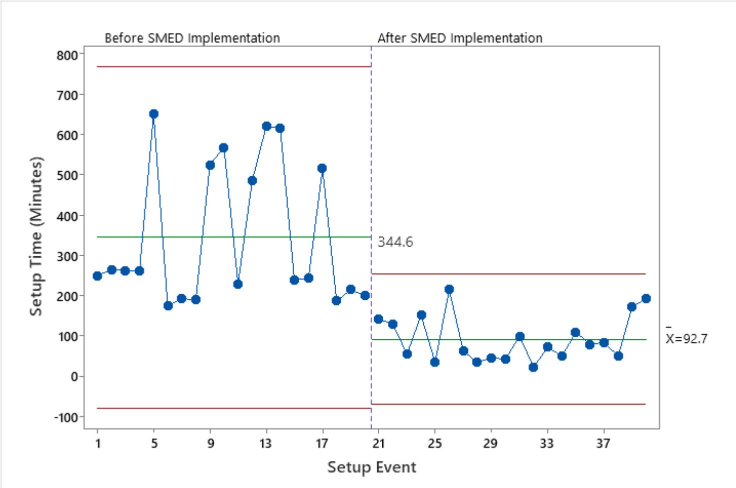

Figure VIII.- Control chart of setup time before and after the SMED Implementation

Even though the model change was reduced to 92.7 min on average, this value is still well above the SMED technique. Therefore, the team investigated why this was considerably high. After a brainstorming session, it was found that the first part of releases consumed 40% of the model changeover time. This was because of the multiple quality rejections of the parts.

When investigating the root cause of the high rate of rejections, it was identified that the measurements varied owing to various factors. Therefore, the team decided to conduct a measurement system analysis (MSA) on different days involving the personnel and instruments used in the release of the machine. The results of the MSA error and the sigma level of the corresponding day are presented in Table IV, which was used to perform a regression analysis in Minitab. Figure IX shows the regression analysis and the corresponding equation.

Day	% Error (X)	Sigma Level (Y)
1	31.72	1.044
2	39.91	0.771
3	23.99	2.246
4	29.82	0.872
5	31.81	0.021
6	40.78	0.472
7	30.03	1.891

Day	% Error (X)	Sigma Level (Y)
11	25.98	2.363
12	25.33	2.56
13	30.66	1.002
14	29.4	1.302
15	36.68	0.448
16	35.58	0.139
17	33.43	0.774

8	23.23	1.98
9	20.76	2.676
10	23.23	1.973
18	20.68	2.017
19	40.12	0.683
20	17.38	2.702

Table IV.- Error of the measurement system and sigma level

The measurement system error had a significant variation, and it had a relationship with the quality level of the process. Regression analysis shows an R-squared value of 71.2%, which means that the measurement system error explains 71.2% of the process's sigma level value.

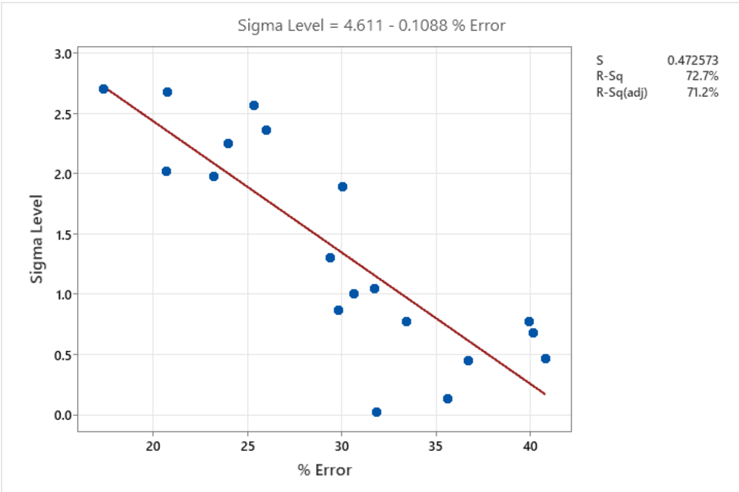

Figure IX.- Regression analysis using the Measurement error (x) vs the Sigma level (y).

3.4. Verify the solution. - Once the solution was developed and implemented, an experimental design was conducted to verify the impact of the model change on compliance with the production schedule. For this purpose, data on compliance with the production schedule was taken for two weeks, and then a comparison was made using a 2-sample t-test in Minitab software. The results are presented in Table V.

	Sample	N	Mean	StDev	SE Mean
	Before	24	0.7742	0.0495	0.010
	After	22	0.9936	0.0162	0.0035
Null hypothesis	H_0: $\mu_1 - \mu_2 \geq 0$				
Alternative hypothesis	H_1: $\mu_1 - \mu_2 < 0$				

Table V.- 2 Sample test and hypothesis tests to validate the solution.

Based on the confirmation run and hypothesis test shown in Table V, it is concluded that the model change time is directly correlated to the compliance with the production schedule. Once the solution was implemented, compliance with the production schedule increased from 77% to 99.36%.

3.5. Control plan. - As the last step of the proposed methodology, a series of Kaizen-type events involving staff from all shifts involved in the model changes were carried out. These events were theoretical-practical training given to quality, maintenance, production, manufacturing and test engineering to notify them about the implemented improvements and the new work method for standardization. Initially, there was no properly documented method to perform the changeover process; after implementing the SMED technique, a work instruction was developed, including a sequential flow with tools, materials and information needed before and after the changeover initiation. It is important to mention that the kaizen events were carried out using the Gemba approach. To monitor and react on time, a board was placed next to the machines to document the setup times, including the challenges and milestones found during the process. Also, an Andon was implemented with a color code properly defined to visually identify the machine's status and support immediately in case any showstopper appears.

4. Discussion of results and conclusions. - The initial information showed that the analyzed plastic injection process had a sigma level of zero, initially having a production schedule compliance rate of 77% on average, below the company's goal. Using the proposed methodology based on Lean sigma, it is concluded that the root cause of the problem was that model changeover times sometimes shoot up to 8 hours, affecting the availability of machinery and flexibility and the ability of the process to adapt to fluctuations in demand. The SMED technique was used to reduce model changeover times and achieve a 75% reduction in setup times, with the fundamental principle of converting internal activities into external ones. In the solution verification step, it was possible to demonstrate that there was a correlation between the reduction of model changes and compliance with the production schedule according to the 2-sample-t test; it was demonstrated with a confidence level of 95% that compliance with the schedule was increased from 77% to 99.36%.

This case study was carried out over eight weeks, solving the root problem with an approach where the contribution or novelty lies in the fact that this approach is oriented to solving problems at the speed of lean, unlike traditional Six Sigma approaches, where projects are based on annual savings and on average improvements can be seen between 6 and 12 months. It is important to mention that companies need to solve problems quickly to reduce Lead time; for example, Kulkarni et al. [22] show an application of traditional Six Sigma, where a company is scraping 10% of the daily production which represents a loss of $10K daily that means a total loss of $200,000 per month, using the traditional approach which took eight months to solve the problem this represented a total loss of over a million dollars compared to the proposed method which would have a loss of $300,000. Guleria et al. [23] applied the traditional Lean Six Sigma approach, showing results in eight months; in this case, the company lost $800,000 versus $150,000 if the proposed approach had been used.

Another scientific contribution proposed by this research is the correlation between the measurement system error and the sigma level of the process, which was presented in the phase of reduction of internal activities of the SMED technique. However, the team managed to reduce the model change time significantly. It was observed that it was still high, so it was decided to investigate in more detail, finding that the root cause was the high rate of rejection, and it was found that the error in the measurement system was an important contributor. It is concluded that the measurement system explains 71.2% of the fluctuation in the sigma level of the process, which means that the measurement system does not correctly classify good and bad parts; bad parts are accepted, and good parts can be rejected. This finding opens a line of research focused on further studying the relationship between these two components and strategies to counteract the error in the measurement system so that the quality of the processes is maintained at acceptable levels. Considering this case study, the measurement system error is ~ 29%; this value means that, on average, 29% of the time, parts are categorized incorrectly; in other words, 29% percent of the parts are rejected and scrapped when these are acceptable. This error can represent a high contribution to the increase of the manufacturing costs of the company, considering only one part number with a scrap cost of $10.53, considering a monthly production of 25,000, if the worst scenario is assumed that 29% of the parts are scrapped because of the error of the measurement system this could be an annual cost of ~$900,000.

This methodology and its approach, including the engineering tools used, can be applied to any manufacturing company around the world. It includes fabrication, powder coating, final assembly, metals, molding, and PCBAs, among other processes.

5. Limitations and future research. - It is important to mention that this research was carried out using a plastic injection molding process; however, the methodology can be used in any manufacturing process. One of the limitations is that for its implementation, the work team must be led by a person with knowledge of Lean and Six Sigma topics, preferably a Black Belt, to be able to guide and direct the team in the right direction and with an analytical and statistical approach. Likewise, it should be noted that a multidisciplinary work team must be dedicated and committed because it requires time to achieve the expected results. The proposed approach initially focused on addressing the main cause of the problem; it is recommended to continue applying the approach to address other identified causes to improve the process continuously. In future research, it is recommended that the effect of the measurement system analysis be investigated at the sigma level of the process to quantify and develop a solution for this cause of variation.

References

[1] M. Bhargava and S. Gaur, “Process Improvement Using Six-Sigma (DMAIC Process) in Bearing Manufacturing Industry: A Case Study,” in IOP Conference Series: Materials Science and Engineering, IOP Publishing Ltd, Jan. 2021. doi: 10.1088/1757-899X/1017/1/012034.

[2] M. Kholil, J. Haekal, A. Suparno, D. S. Oktaandhini, and T. Widodo, “Lean Six sigma Integration to Reduce Waste in Tablet coating Production with DMAIC and VSM Approach in Production Lines of Manufacturing Companies,” International Journal Of Scientific Advances, vol. 2, no. 5, 2021, doi: 10.51542/ijscia.v2i5.8.

[3] D. Zhang, S. Chen, and Y. Xu, “Study on the improvement of single minute exchange of die based on lean production,” in Seventh International Conference on Electromechanical Control Technology and Transportation (ICECTT 2022), SPIE, 2022, pp. 101–110. doi: 10.1117/12.2645572.

[4] K. F. Barcia, L. Garcia-Castro, and J. Abad-Moran, “Lean Six Sigma Impact Analysis on Sustainability Using Partial Least Squares Structural Equation Modeling (PLS-SEM): A Literature Review,” Sustainability (Switzerland), vol. 14, no. 5, 2022, doi: 10.3390/su14053051.

[5] A. Horzela and J. Semrau, “Using Tools to Improve Logistics and Production Processes in a Selected Construction Company,” European Research Studies Journal, 2021, doi: 10.35808/ersj/2100.

[6] Y. Trakulsunti, J. Antony, R. Jayaraman, and G. Tortorella, “The application of operational excellence methodologies in logistics: a systematic review and directions for future research,” Total Quality Management and Business Excellence, vol. 34, no. 5–6, pp. 538 – 557, 2023, doi: 10.1080/14783363.2022.2071695.

[7] S. S. Chakravorty and D. N. Hales, “Sustainability of process improvements: an application of the experiential learning model (ELM),” Int J Prod Res, vol. 55, no. 17, pp. 4931 – 4947, 2017, doi: 10.1080/00207543.2016.1277278.

[8] A. C. Tonini, M. De Mesquita Spínola, and F. J. B. Laurindo, “Six sigma and software development process: DMAIC improvements,” in Portland International Conference on Management of Engineering and Technology, 2006, pp. 2815 – 2823. doi: 10.1109/PICMET.2006.296875.

[9] R. L. Matthews and P. E. Marzec, “Continuous, quality and process improvement: disintegrating and reintegrating operational improvement?,” Total Quality Management and Business Excellence, vol. 28, no. 3–4, pp. 296 – 317, 2017, doi: 10.1080/14783363.2015.1081812.

[10] H. Lebovits and J. Teal, “Considering Equity in Public Process Improvement Trainings,” Public Integrity, vol. 22, no. 6, pp. 555 – 574, 2020, doi: 10.1080/10999922.2020.1719807.

[11] M. A. S. Ribeiro, A. C. O. Santos, G. da F. de Amorim, C. H. de Oliveira, R. A. da Silva Braga, and R. S. Netto, “Analysis of the implementation of the single minute exchange of die methodology in an agroindustry through action research,” Machines, vol. 10, no. 5, p. 287, 2022, doi: https://doi.org/10.3390/machines10050287.

[12] J. Nikolić, M. Dašić, and M. Đapan, “Smed as an indispensable part of lean manufacturing in the small and medium enterprises.,” International Journal for Quality Research, vol. 17, no. 1, 2023, doi: 10.24874/IJQR17.01-16.

[13] P. Teixeira, J. C. Sá, F. J. G. Silva, L. P. Ferreira, G. Santos, and P. Fontoura, “Connecting lean and green with sustainability towards a conceptual model,” J Clean Prod, vol. 322, p. 129047, 2021, doi: 10.1016/J.JCLEPRO.2021.129047.

[14] J. L. García-Alcaraz, G. Alor-Hernández, C. Sánchez-Ramírez, E. Jiménez-Macías, J. Blanco-Fernández, and J. I. Latorre-Biel, “Mediating role of the six sigma implementation strategy and investment in human resources in economic success and sustainability,” Sustainability (Switzerland), vol. 10, no. 6, 2018, doi: 10.3390/su10061828.

[15] A. Al-Atiyat, A. O. Ojo, and P. C.-H. Soh, “Impact of six sigma critical success factors on productivity improvement through absorptive capacity in the manufacturing industry in Saudi Arabia,” International Journal of Productivity and Quality Management, vol. 32, no. 4, pp. 536 – 556, 2021, doi: 10.1504/IJPQM.2021.114267.

[16] F. Estrada-Orantes and N. Alba-Baena, “Creating the lean-sigma synergy,” in Lean manufacturing in the developing world: methodology, case studies and trends from latin America, 2014, pp. 117–134. doi: https://doi.org/10.1007/978-3-319-04951-9_6.

[17] O. C. Gracia and J. A. T. Moctezuma, “Implementación de la metodología Lean Sigma en un proceso de ensamble de engranes y cadenas: Caso de estudio,” CULCyT: Cultura Científica y Tecnológica, vol. 19, no. 3, pp. 23–32, 2022, doi: https://doi.org/10.20983/culcyt.2022.3.2.3.

[18] O. Celis-Gracia, J. L. García-Alcaraz, F. J. Estrada-Orantes, L. Avelar-Sosa, N. G. Alba-Baena, and F. Hermosillo-Villalobos, “Reduction of Setup Times in a Metal Fabrication Company Using a Lean-Sigma Approach,” Enfoque UTE, vol. 15, no. 3, pp. 41–48, Jun. 2024, doi: 10.29019/enfoqueute.1027.

[19] “Index.” Accessed: Jan. 29, 2024. [Online]. Available: https://index.org.mx/

[20] G. C. P. Condé and J. C. de Toledo, “Continuous Improvement Related Performance: A Bibliometric Study and Content Analysis,” in Springer Proceedings in Mathematics and Statistics, G. dos Reis J.C., M. F. F.G., and V. J. M., Eds., Springer, 2023, pp. 211 – 222. doi: 10.1007/978-3-031-47058-5_17.

[21] S. D. Kulkarni et al., “Enhancing the process capability of machining process of boring tool holder by application of six sigma methodology,” Mater Today Proc, vol. 52, pp. 329–338, 2022, doi: 10.1007/978-3-319-92267-6_45.

[22] P. Guleria, A. Pathania, S. Sharma, and J. C. Sá, “Lean six-sigma implementation in an automobile axle manufacturing industry: A case study,” Mater Today Proc, vol. 50, pp. 1739–1746, Jan. 2022, doi: 10.1016/J.MATPR.2021.09.177.

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