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A Plan-Do-Check-Act Based Process Improvement Intervention for Quality Improvement

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ABSTRACT Waste from raw materials has a direct influence on the final price of a product. However, since waste has no added value to products, customers are unwilling to pay for it. Reducing waste along the production process and supply chain allows companies to decrease costs and remain competitive in product prices. This research is conducted in a medical device manufacturing company located in Tijuana (Mexico). The company found a negative variation in part number 9540, a metallic foil used for hot stamping. During inventory cycle counts, the company found that they were purchasing rawer material than necessary due to a 50% of waste generated along the production process. We implemented two process improvement methodologies, namely Practical Process Improvement (PPI) and the Plan-Do-Check-Act model, to eliminate 100% of the raw material waste, specifically regarding the foil's waste. The improvement project comprised two phases: a) adjusting the parameters of the hot foil stamping machine and b) replacing the hot foil stamping machine with a pad printing machine. In our research, the PPI methodology is presented in 8 detailed stages as a simple problem-solving method, in contrast with five stages reported in other documented cases. This case study presents how a company can apply continuous improvement programs and its managerial implications, even without having a structured and defined systems for quality, such as Six Sigma or Lean Manufacturing implemented. After the two implementation phases, the improvement project led to economic savings of \$165,000 in a year.

INDEX TERMS Return of investment (ROI), cost reduction, deming cycle, kaizen, medical devices company, PDSA, PDCA, scrap, validation process, Pareto and Ishikawa charts, Mexican manufacturing industry.

I. INTRODUCTION

A lean culture requires reduction, management, and even elimination of all kinds of waste in manufacturing. A lean approach to production helps companies comply with a sustainable focus by making their processes cleaner [1]. Lean tools (LT) are parallelly employed along with other improvement methods, including lean manufacturing (LM) [2]–[5], six sigma (SS) [6]–[10], total quality management (TQM) [11]–[14], and kaizen. All of them aimed

to enhance key performance indicators and waste reduction. All these process improvement methods are widely reported and studied in other contexts than the manufacturing industry [3], [6], [15], [16], including the extractive industry [17] and the services sector [10], [16], [17]. Additionally, the Plan-Do-Check-Act (PDCA) model is also known as Plan-Do-Study-Act (PDSA) and is an LM technique for quality improvement [18].

This research proposes a case study to solve a practical problem using continuous process improvement tools under a quantitative approach, the Practical Process Improvement (PPI) methodology. The study specifically focuses on

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the hot stamping problem of packaging boxes. This case study presents how a company can apply continuous improvement programs and its managerial implications, even without having a structured and defined systems for quality, such as Six Sigma or Lean Manufacturing implemented. After the two implementation phases, the improvement project led to economic savings of \$165,000 in a year. The ultimate goal of the improvement intervention was to reduce foil waste by achieving the following objectives:

- a) Reduce at least 20% of foil waste at the hot foil stamping process.
- b) Documenting raw material consumption on an Engineer Change Order (ECO).
- c) Assess the technical feasibility of replacing hot foil stamping machines with pad printing machines.

Our project was conducted in two phases, and we used PPI in the first phase. PPI is at the core of the organizational culture and all improvement projects in the company where the case study is conducted. In literature, documented applications regarding the PPI methodology are scarce, so this article is aimed to document in detail that methodology, its advantages, limitations, and managerial implications, compared to other more complex methodologies and techniques such as SS or LM. It is possible to verify that a simple methodology adequately applied in a company, where the quality culture is limited by industrial sector regulations, can offer acceptable solutions if compared with complex methodologies for solving problems.

PPI comprises eight steps and is based on the Deming Cycle or PDCA Cycle. As depicted in Figure 1, the steps in PPI include a) mission statement, b) define the current process, c) simplify the process, d) analyze data, e) find solutions, f) test solutions, g) standardize, and h) plan [19]. PPI favors teamwork to solve real problems and successfully improve processes.

The remainder of this document is organized as follows: Section 2 presents a literature review, section 3 describes the research context and the research methods, section 4 introduces the case study, section 5 discusses our results, section 6 states the limitations of the case study, and finally, in section 7 we propose our research conclusions and recommendations for future work.

II. LITERATURE REVIEW

A. LEAN MANUFACTURING AND SIX SIGMA

LM operates under the principle of “doing the right things correctly.” From this perspective, LM ensures effectiveness in production, as companies use fewer resources to meet the same production goal while contributing to environmental care. LM focuses on maintaining a productive supply chain that only has added-value activities, thus avoiding waste at all costs and acknowledging the role of employees who generate improvement suggestions [11]. Additionally, LM is proof that environmental impact reduction does not conflict with cost reduction. Both strategies work perfectly well together [1].

The underlying principle of SS implies “doing the right things correctly and error-free.” Namely, SS focuses on controlling and managing processes to reduce variation and thus achieve zero defects. It is not surprising that the SS philosophy is often studied from sustainability and thus implemented in green processes for emission reduction. For instance, the Green Lean Six Sigma (GLSS) model is an eco-friendly approach to reducing carbon footprints while producing high-specification products with little to no variation in the process and zero defects [18].

Companies may have different objectives when implementing process improvement projects, yet the overall goals usually remain the same: save time and costs, increase customer satisfaction, and raise employee productivity. Moreover, process improvement is not achieved in a definite period; it is a continuous journey within the LM approach. The chief objectives in lean process improvement include waste reduction, process time optimization, and adding more value to products. In their book on the Toyota production system, authors James P. Womack, Daniel T. Jones, and Daniel Roos were the first to have coined the lean expression approach [19]. A lean approach must be an organizational state of mind to be effective and all departments and processes must be aligned with the lean strategy and continuously enhance their processes.

B. REGULATIONS FOR MEDICAL DEVICE MANUFACTURING

In Mexico, the manufacturing industry is one of the essential pillars of the economy, accounting for around 17% of gross domestic product (GDP). In 2020 alone, the Mexican manufacturing sector attracted foreign direct investment of nearly US\$12 billion and employed more than nine million workers. Medical device manufacturing represents 1.5% of the sector and generates more than 130,000 jobs. The medical device manufacturing industry operates under multiple regulations. Regarding manufacturing systems in Tijuana, factories respond to international regulations (the US and European norms) and Mexican regulations. Hence any improvement proposal must be aligned with these policies and consequently respect and follow international and domestic protocols. On the one hand, there must be compliance with the US Food and Drug Administration (FDA)’s 21 CFR, namely part 11 (regulations for electronic records and electronic signatures) [20], part 210 (current good manufacturing practices for drug processing, packaging, and holding) [21], part 800 (regulations for medical device manufacturing) [22], and part 820 (regulations for quality systems) [23].

Another important regulation to be followed is medical device directive 93/42/EEC-MDD [24], from the EU Medical Device Directive. Other international regulations include ISO norms 13485 [25] and 9000 [26]. Finally, domestic regulations include norms NOM-137-SSA1 [27] and NOM-241-SSA1 [28], supervised by the Federal Commission for the Protection against Sanitary Risks (COFEPRIS, by its Spanish acronym).

In 2014, the manufacturing industry in Mexico reached production levels of 15,220 million USD [29]. The added value of a medical device product represents 20% when the equipment is disposable and up to 36% in electronic devices. Also, of the raw materials used for manufacturing medical devices, 36% are generally imported in disposable devices and up to 92% in the case of electronic devices. According to the Global Trade Atlas [29], in 2014, Mexico exported 7,699 million USD worth of medical products, positioning itself as the ninth-largest exporter worldwide, the largest exporter in Latin America, and the leading supplier for US.

The main products exported included surgical, dental, veterinary instruments and devices, representing 76% of the medical equipment exports. In terms of international trade that same year, Mexico became the second largest exporter worldwide of tubular needles for sutures, the fourth largest exporter globally of surgical furniture, and the fifth largest exporter of syringes, catheters, and similar instruments.

C. CASE STUDIES FOR CONTINUOUS IMPROVEMENT

Currently, customers demand price reduction and higher quality, which leads administrators to remain competitive and profitable. Vu [32] documented a project providing warranted information to cost savings approach from lean implementation in a manufacturing facility producing an aseptically-filled eye care solution as part of the ophthalmic device company network of product plants, incorporating lean metrics in the manufacturing operation. The research reports cost savings from Overall Equipment Effectiveness (OEE) improvements, decreasing waste related to excessive inventory in the manufacturing line (work in process inventory), multi-batch production systems, cluttered floor space, and unbalanced cycle times assembly areas. Vu applied a Value Stream Map (VSM) as follows: (a) look at the entire production process from start to finish, (b) evaluate each area touching the product, and (c) identify waste factors. VSM is one of the most important visual tools to illustrate the entire value stream from customer order entry until the finished good is in a facility. The kaizen team was in charge of waste reduction. The implementation of lean operations proves cost savings, achieved by a reduction in process inefficiencies, machine downtime, component scraps, and product rework. Vu states that numerous advantageous features (related to employees, customers, and shareholders) from lean linked to business savings were not quantified.

Another case study analyzing continuous improvement in medical device manufacturing is presented by Brown *et al.* [33]. They compared a range of quality and continuous improvement strategies and investigated whether there was the best strategy for use within the medical devices sector. The value of their research was proposing a link between a given organization's favored leadership style and the applicability of a particular continuous improvement strategy. They found the quality and continuous improvement strategies can be differentiated in their cultural or process focus. Moreover, the favored leadership style of an

organization may play a part in determining which strategies are likely to be most appropriate. From the medical device and healthcare product perspective, regulatory and purchasing considerations will have a role in determining the strategy adopted.

Also, Grewal [34] implemented VSM as the primary tool to apply a LM initiative in a small company. They were mapping the company's activities, identifying opportunities for improvement, and then undertaking an improvement program. The takt time, lead time, cycle time, setup time (by applying SMED, Single Minute Exchange of Die), and inventory level (WIP) was analyzed, reduced, and controlled, facilitating continuous improvement wherever possible.

Continuous improvement also is possible by applying Six Sigma, identified as a complex program. Antony, Gijo, & Childe [35] implemented this methodology in high precision and critical process in the manufacture of automotive parts, improving the first pass yield from 85% to 99.4%. That improvement represented savings by \$70,000 per year and benefits of improved quality in returns and sales. They collected data on all possible causes. For finding a relationship, techniques such as regression analysis, hypothesis testing, Taguchi methods, gauge repeatability and reproducibility study, classification, and regression tree techniques were applied. Six Sigma is a tool for complex problems where causes are not obvious. A high level of technical ability is required for the benefits to be gained.

Design of Experiments is another powerful tool for Six Sigma methodology. Prashar [36] proposed a conceptual Six Sigma/DOE hybrid framework to integrate Six Sigma, Taguchi methods, and Six Sigma DMAIC (Define, Measure, Analyze, Improve, and Control) for process improvement in complex industrial environments. Prashar presented an illustrative case study to test the proposed framework. In phase 1 (define and measure) he identified critical quality by applying Pareto charts and process capability analysis. In phase 2 (analysis) was supported by Shainin Component Search Tool (BOB 'best of best', and WOW 'worse of worse'); in phase 3 (improve), Taguchi orthogonal arrays design was incorporated for designing experiments; and finally, a control plan to ensure sustained gains. Its theoretical contribution resides in a novel proposal to introduce the user-friendly and straightforward DoE tools into a well-established process improvement framework to enhance the effectiveness of Six Sigma projects.

III. METHODS

PPI is an eight-step methodology (see Figure 1) based on the PDSA Cycle. It was proposed by Edward Zuniich in 1989 when assuming the control of the Total Quality and Leadership program at the US Navy. Zuniich borrowed the Plan-Do-Check-Act (PDCA) model from Dr. J. Edwards Deming and proposed an updated version in which he replaced the Study stage with the Check stage. The first company to have ever implemented the PDSA cycle was Thermo Fisher Scientific in 2002, back then known as

Thermo Electron. The model has been remarkably successful since its implementation, and the company still uses it in all its worldwide locations. Since then, multiple other organizations have successfully adopted the model [18], [36].

The eight steps comprised in PPI are further explained below:

Step 1: Mission statement. Identify the problem to be solved, set limits, develop metrics, and fix objectives.

Step 2: Define the current process. Identify key process steps and build a basic flowchart of the process.

Step 3: Simplify the process. Look for obvious waste and problems and remove all said waste and exposed problems (i.e. take out the ripe fruit). Focus on reducing waste and time and analyze the added value of the process.



FIGURE 1. Eight steps for PPI, PDSA-cycle-based. Based on [19].

Step 4: Analyze data. Identify the possible causes of the problem, use improvement tools, and check the data. Improvement tools may include the following:

- The 80-20 rule or Pareto principle. The underlying assumption of this rule is that 80% of consequences come from 20% of the causes. Namely, it is neither practical nor productive to try to fix all the problems of a process. A Pareto chart is a compulsory tool for PPI implementation.
- Fishbone diagram. It is a cause-effect diagram that helps companies identify the possible causes of a problem. A fishbone diagram is a tool for brainstorming and looks just like a fish skeleton, with the problem at its head and the causes to the problem feeding into the spine [18]. This diagram is also compulsory for PPI implementation.
- Quick vote. Each participant has six points. He/she can assign a maximum of four points to a single problem cause, while the remaining two points can be assigned to other causes.
- The five whys method. Companies need to ask the right questions to solve a problem. The five whys is an iterative interrogative method to solve a problem by drilling down to its root cause by asking “Why?” five times. Then, when a solution becomes apparent, companies

confirm it with the data and use it to prevent recurring problems.

Step 5: Propose solutions. Solutions to a problem must come directly from both data analysis and the conclusions proposed in step 4. In step 5 of PPI, organizations must develop two or three solutions to solve the causes to the most significant problems.

Step 6: Test solutions. Use data to evaluate solutions, ensure the objectives are met, and avoid costly errors. Conduct a PDCA test to ensure the solutions will have the desired results and avoid costly errors.

Step 7: Standardization. Implement the new methods and processes to sustain improvements. All new actions must be appropriately documented in a new flowchart for process implementation, management, and control. This new document is vital to monitor improvement actions and results. Also, in this step, it is essential to consider the following resources:

- Implementation plan. All actions need to implement solutions, i.e. what? who? and when?
- Management plan. Monitor metric results in the process and outputs.

Step 8. Future plans. Document all new opportunities for continuous improvement and future PPI projects. These new ideas are noted down during the parking lot or parking space in meetings, and they generally concern problems that lay outside the scope of the project due to insufficient data.

If compared to SS, PPI relies on fewer tools. Hence, it is easier to implement in a wide range of projects in different organizations. Figure 2 introduces a useful diagram that can help companies choose the improvement program that best meets their needs and fits their particular characteristics.

PPI methodology has been applied successfully in other case studies and companies; Vu *et al.* (2007) [32] present the applied PPI methodology for Embedded Real-Time Software. Here, presents PPI approach to the incremental improvement of the quality of the software development process. Adopting a TQM approach to software process improvement emphasizes the role of embedded software in a more extensive product development context. One of the critical concerns in planning practical software process improvement was measuring quality; they proposed two classes of metrics related to the quality of the software process and products and the other for measuring the rate of improvements in the process.

In Japan, PPI methodology was applied to monitor and analyze solvent emissions from metal cleaning processes [33]. Solvent emission mechanisms from metal cleaning processes were analyzed to support process improvement aimed at emission reductions.

Between 2012 and 2015, Thermo Fisher Company saved more than \$170 million with PPI Business System considered productivity savings. This system “empowers every employee to solve problems, large and small, for the organizations, creating a culture of continuous improvement” [34]. This initiative has represented a reduction of 14 tons per year

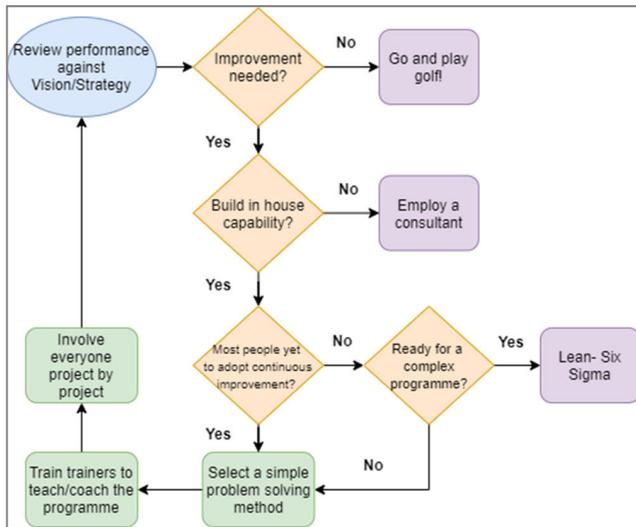


FIGURE 2. How to select a good improvement program.

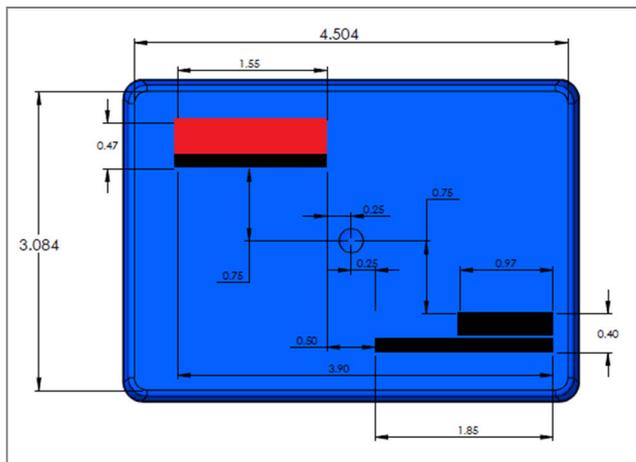


FIGURE 3. Dimensional specifications of box stamps.

in the production of hazardous waste for special handling; additionally, the reduction of 51 million linear feet of paper waste.

IV. RESULTS

Process improvement techniques are widely implemented in Mexican manufacturing companies, especially in Mexico/US border regions. The company where we conducted this case study is a medical device manufacturer located in Tijuana, a highly industrialized region. The study specifically focuses on the hot stamping problem of packaging boxes. Finished medical devices are packed in plastic boxes previously hot-stamped with tin foil with the company’s logo. Figure 3 shows a two-dimensional view of a packaging box along with its dimensional specifications (inches).

The red and black parts mark the stamped areas. Figure 4 depicts a tridimensional view of the same box. Aware of the importance of efficient resource utilization, the company operates under a continuous improvement

philosophy through periodical kaizen events, known as PPI projects. During a regular meeting, the assembly department highlighted the potential opportunity to improve the hot stamping process of the packaging boxes. Hot foil stamping as a printing technique uses hot dies to press a metallic print and foil onto the surface material (e.g. boxes). Foils are multilayered coatings that transfer to the surface of the boxes; however, the finance department noticed that the foils showed negative variations during the cycle counts. It was found that foil waste had been causing up to 50% losses and was an increasing problem costing the company \$4,700, \$5,000, \$5,500, and \$6,000 every month in the last quarter.

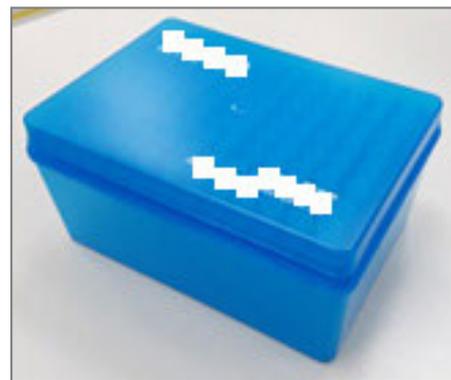


FIGURE 4. Finished product.

The underlying justification of the improvement intervention was chiefly related to economic reasons. Hence, to properly define and measure the magnitude of the problem, the company analyzed costs, revealing annual losses of up to \$67,050 due to foil waste alone. Following the analysis, the company realized that the production department had failed to report any foil waste, which is why the company ignored the foil shortage.

The ultimate goal of the improvement intervention was to reduce foil waste by achieving the following objectives:

- a) Reduce at least 20% of foil waste at the hot foil stamping process.
- b) Documenting raw material consumption on an Engineer Change Order (ECO).
- c) Assess the technical feasibility of replacing hot foil stamping machines with pad printing machines.

Additionally, it is vital to consider and fully understand the implicit challenges of both measuring raw material consumption and determining optimal waste reduction rates and the implications of replacing the stamping technology.

Some of the variables involved in the hot-foil stamping process include the printing/stamping area, foil unit price, stamping speed, state of foil rolls, machine alignment, maintenance technicians, and machine operators. Also, it is essential to mention that the company operates six hot stamping machines that use five different types of foil. The improvement intervention discussed in this case study only concerns

one type of foil (no. 9540), yet the method can be replicated to propose improvements with other foil parts further. Finally, the improvement intervention comprised two phases, and PPI was used in the first phase.

A. PHASE 1. PROCESS IMPROVEMENT IN HOT FOIL STAMPING MACHINE

Step 1. The goal of the improvement project was to reduce at least 20% of the waste generated during the hot stamping process that uses part no. 9540, since it was found that waste from this part generated a third of annual economic losses. If the goal is achieved, the company is expected to move from negative to positive variations in cycle counts. According to figure 5, the Pareto chart presents product 412 with the highest volume of production. This product uses ink 9540 in the hot stamping process. Product 412 represents 50% of the cost related to ink 9540.

Step 2. Define the current process. The hot foil stamping process begins with the production department requesting foil to the warehouse. Then, the warehouse must send the material to the maintenance department to be placed in the stamping machine by maintenance technicians. However, since the company often runs out of foil earlier than expected, maintenance technicians must readjust the parameters of the hot stamping machine to use foil scrap. Moreover, the machine parameters are not standardized and depend on who calibrates the machine, either maintenance technicians or operators. Figure 6 illustrates the workflow diagram of the foil request process, in which the orange and yellow phases indicate the problem.

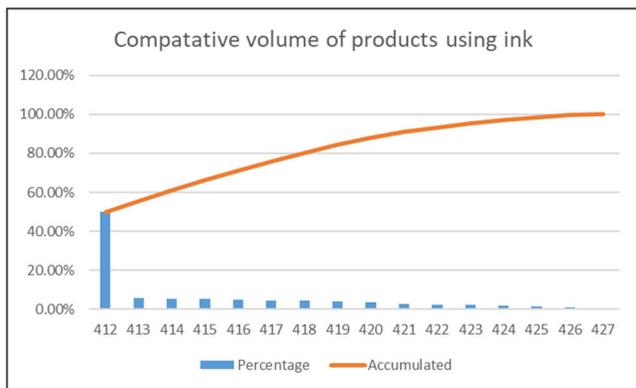


FIGURE 5. Pareto chart.

Step 3. Look for obvious problems and waste. We found that the stamping machine underwent unnecessary adjustments. Production was maintained using only one machine for the analysis process only (there are four hot stamp machines), thus avoiding constant adjustments as foil rolls were installed. Likewise, the stamping machines needed to be realigned to reduce waste.

Step 4. To identify the root cause of the problem, we built a fishbone or Ishikawa diagram related to foil scrap, as depicted in Figure 7.

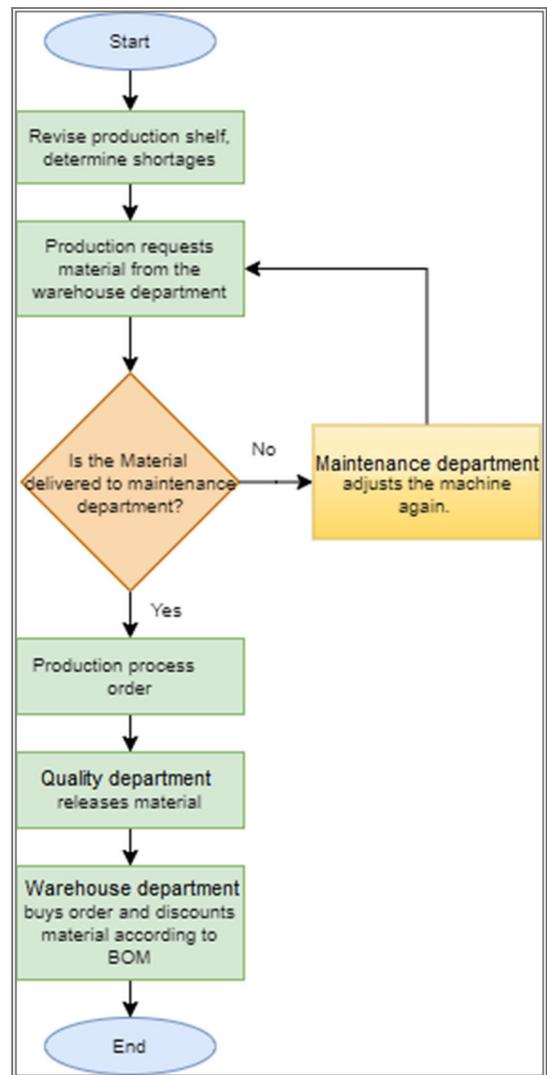


FIGURE 6. Workflow diagram for foil replenishment.

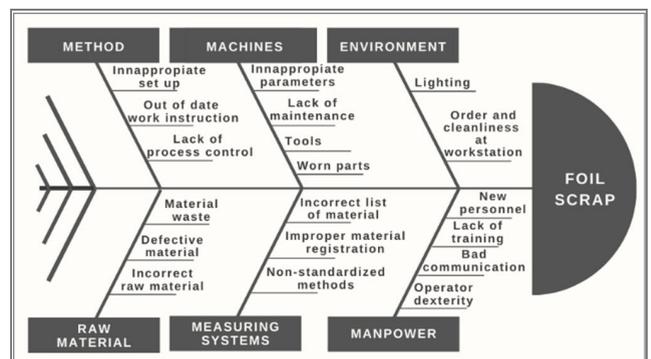


FIGURE 7. Ishikawa diagram related to foil scrap.

Method. The company uses nor a standardized machine calibration method neither an operations sheet to help technicians and operators install the foil rolls on the machines. Moreover, it is not customary to monitor or supervise machine adjustments.

Machine. Current machine parameters are not correct: the company lacks a standardized process for calibrating the stamping process. Preventive maintenance is not customary; as only specific machine parts are treated. Current maintenance tools and some machine parts are worn out, which prevents the machines from operating correctly and contributes to waste generation.

Environment. The stamping machine requires deep cleaning and hardware maintenance. Lighting is poor (one 60-watt lamp, only), and operators are past middle age.

Materials. The current process makes excessive use of raw material, which is also either incorrect or defective. When the raw material is incorrect, the stamping must be reworked. In the case of defective foil rolls, production is stopped, and idle time increases.

Measuring system. The company lacks pre-established methods to both operate the hot foil stamping machines and supervise that all the materials from the material checklist are used during the hot stamping of the boxes. Overall, the company lacks visibility regarding what is done during the hot foil stamping process. Finally, the material checklist states an excessive amount of foil for box stamping.

Labor. Communication is poor. Operators are not adequately trained to operate the stamping machines according to the materials listed on the checklist. There is no robust training for new maintenance technicians. Additionally, the company lacks updated training following machine improvements. Finally, maintenance technicians lack the necessary skills to solve machine-related problems; therefore, they cannot determine whether it is necessary to report a problem immediately. Table 1 summarizes our analysis of the problem.

Step 5. Find solutions, assess the feasibility of solutions based on data, and make a plan. We analyzed the hot foil stamping problem in the assembly area, and we verified the logo's dimensions (see Figure 1, i.e. 4.2 inches per logo stamp) stamped on the box lids. After calculating the amount of raw material needed for box stamping, we found that the company orders more foil than necessary.

Example of raw material calculations: Product no. 412 (a plastic box) requires 20 ft of foil per box; each box contains ten lids. Hence, considering the logo dimensions (i.e. 4.2 inches), the company needs 42 inches of foil to stamp ten boxes. To convert inches into feet, $42 / 12 = 3.5$. Then, we add 0.2 ft due to roll adjustments. In total, only 3.7 feet of foil should be needed to stamp one box; thus, indicating a waste of 16.3 ft of foil per box for the product no. 412 alone and for this foil part alone. The hot foil stamping machine consumes the foil excess due to mechanical failures. The case study company annually produces 2.9 million lids and 462,754 boxes, whereas foil consumption reaches 2.4 million ft, 404,233 ft of which are waste.

As shown in Table 2, this problem leads to total process expenses of 130,918.21 USD, \$18,594.71 of which are exclusively due to foil waste. Table 3 list the waste for the product no. 412 before the improvement.

TABLE 1. The five "Whys?".

Why?	Because
1. Why is there a foil waste problem?	Because the company experiences monetary losses due to excessive use of foil roll no. 9540.
2. Why are there monetary losses due to excessive foil roll (part) no. 9540?	Because mechanical failures in the hot stamping machines are frequent, the material checklist does not state the correct material needed in the stamping process.
3. Why are mechanical failures so frequent, and the material checklist does not state the correct quantities of material needed in the stamping process?	Because maintenance technicians are not trained to repair or adjust the machines quickly, they do not formally report mechanical failures.
4. Why are maintenance technicians not trained to quickly repair or adjust the machines and formally report mechanical failures?	Because the company lacks formal training for new maintenance technicians, and technicians do not formally report losses due to machine adjustments.
5. Why does the company lack formal training for new maintenance technicians who do not report losses due to machine adjustments?	Because company staff is not aware of the importance of making savings in raw materials, and adequately inform of machine anomalies.

TABLE 2. Hot foil stamping expenditure projections before improvement.

Hot stamp foil part no. 9540 expenditure projections for the product no. 412. Year 0 (before improvement)	
Number of lids	2'909,622
Number of boxes	462,754
Usage (ft)	2'441,815
Foil price (per ft)	\$0.046
Foil expenses	\$112,323.49
The total cost of process (with waste)	\$130,918.21

TABLE 3. Hot foil stamping waste before improvement.

Hot stamp foil part no. 9540 waste for the product no. 412. Year 0 (before improvement)	
Waste (ft)	404,233
Waste expenses	\$18,594.71

Step 6. Test solutions. Considering the data gathered during the analysis, the company decided to implement a training program without delay. After testing said solution, expenditure projections for the hot stamping process changed noticeably, as indicated in Table 4. Table 5 list the waste for the product no. 412, after phase 1 of improvement.

TABLE 4. Hot foil stamping expenditure projections following improvement.

Hot stamp foil part no. 9540 expenditure projections. Year 1 (following phase 1 of improvement)	
Number of box lids	2'009,622
Number of boxes	462,754
Usage (ft)	835,723
Foil price (per ft)	\$0.046
Foil expenses	\$38,443.26
The total cost of process (with waste)	\$41,860.00

TABLE 5. Hot foil stamping waste after phase 1.

Hot stamp foil part no. 9540 waste. Year 1 (after phase 1 of improvement)	
Waste (ft)	74,277
Waste expenses	\$3,416.74



FIGURE 8. Hot stamping machine and pad printing machine.

Step 7. Define new process. Maintenance technicians and operators were trained in the new machine calibration process using visual aids. The aids also helped standardize the machine calibration process.

Step 8. Future plans. Even though remarkable improvements were made in the hot foil stamping process, the company found it interesting to further analyze other improvement measures. Hence, we performed an analysis to determine the feasibility of substituting the hot foil stamping technology for pad printing. The improvement project then moved to the second phase. For comparison purposes, Figure 8 illustrates an example of the hot stamping machine and the pad printing machine used in the study. The pad printing mechanism is similar to stamping, yet the former does not require foil but rather cold liquid ink.

B. PHASE 2. IMPROVING THE PAD PRINTING PROCESS

The second phase of the project took place one year following the implementation of the first phase. According to our estimations, summarized in Table 6, substituting hot foil

TABLE 6. Expenditure projections for pad printing technology at phase II of the improvement project.

Expenditure projections for pad printing. Year 2 (following phase II of improvement)	
Number of lids	2'009,622
Number of boxes	462,754
Ink usage (ft ²)	50,173.20
Ink expenses (ft ²)	\$0.023
Projected ink expenditures	\$6,472.34
Savings concerning year 1	\$35,387.66

TABLE 7. Return of the investment (ROI) values.

Amount invested	\$25,000.00
Amount returned	\$35,387.66
Investment gain	\$10,387.66
Return of Investment (ROI)	41.55%
Profit	29.35%
Invested	70.65%

stamping technology for pad printing technology would lead to more than \$35,000 of annual savings for the company.

The company made an initial investment of \$25,000 to purchase and install three pad printing machines (in replacement of four tamp machines) – returns on investment (ROI) were expected eight months following the implementation of the new printing process. According to the values presented in Table 7 and Equation (1), the annualized ROI is 41.55%.

$$ROI = (GI-CI)/CI \tag{1}$$

Where GI = Gain from Investment and CI = Cost of Investment.

Compared to year 0, the total cost of the process in year 1 (phase 1 of improvement project) led to an annual savings of 89,058.21 USD. In turn, if compared to year 1, the total cost of the process in year 2 – i.e., with the new printing technology – could bring the company \$35,387.66 annual savings. In total, the entire improvement project – i.e. phases 1 and 2 – led to \$124,445.87 in savings.

The main goal of the improvement project was to implement a solution to reduce at least 20% of foil waste generated during the hot foil stamping of boxes used to package medical products. After applied the two phases, the project managed to reduce 100% of said waste, considering only wasted foil. Moreover, there is no such concept as ink waste in the new printing process. In the project’s first phase, we tracked and adjusted foil consumption using an ECO on Agile. Moreover, the new printing process was implemented without difficulty. Finally, pad printing was a viable low-cost solution, with significant returns on investment in less than a year.

Another vital implication considering the Lean Manufacturing approach is reducing the time required to produce lids, the same volume of production with fewer workers. Table 8 compares indicators as the number of machines, the number of workers, the number of lids produced per machine per day working with the traditional process

TABLE 8. Hot stamp versus pad printing machine.

	Hot stamp machine	Pad printing machine
Work shifts	2	2
Machines	4	3
Workers	8	6
Lids produced per machine per day	2771	2078

(hot stamp machine), and the improved process (pad printing machine). The improved process represents 4,800 fewer person-hours per year. Additionally, now it is only required the setup of the machines at the beginning of each shift. In the previous method, the adjustments were also made randomly.

It is important to note that a two-day Kaizen event was held over a weekend to ensure a proper equipment function during the production process. The six operators of the new machines, three technicians from the maintenance area, two supervisors from the production area, and the manufacturing and maintenance engineers participated in this event, considering coverage of the two work shifts (Monday to Friday from 7-17 hours and from 5:30 p.m. to 1:30 p.m.). In Mexico, the working day is 8 hours a day, six days a week, working a total of 48 hours a week. However, under the maquiladora regime, shifts usually are 10 hours a day for the morning shift and 9 hours a day for the mixed shift (evening-night), with a total of 50 and 45 hours respectively per shift. In both cases, it includes 30 minutes for lunch, a 15-minute break, and a 10-minute break, so operators have a 55-minute break per shift. This represents an effective 9 hours and 5 minutes of work for the morning shift and 8 hours and 5 minutes for the mixed shift (1030 available minutes per day, per machine, a production of 2078 lids per machine, and a tack time of 2 lids per minute per machine).

V. DISCUSSION

Lean Manufacturing focuses on the process, emphasizes efficiency (improving process flow), and aims to eliminate waste and increase the process flow. While Six Sigma focuses on outputs, it emphasizes efficiency (quality), and its goal is to eliminate defects by reducing variability. Practical Process Improvement (PPI) methodology allows rapid improvements, approaching Lean Manufacturing even considering no formal generalized continuous improvement program. PPI is a simple problem-solving method that can be used with basic training. It is possible to improve indicators related to cost reduction, waste, defects, setup, process time, and the improvement of the process flow. To achieve this, specific but not limited to Lean Manufacturing and Six Sigma tools are applied.

However, as an administrator, the project management leader must decide the relevance of the projects according to the company’s priority indicator, aligned with the company’s vision and strategy. In this case, the strategic priority of the company was focused on reducing costs. Similarly, with the improvement, it was possible to achieve a positive impact

TABLE 9. Comparative cases analysis.

Authors	Contributions	Limitations
Vu (2007)	Lean Manufacturing, OEE, VSM, Kaizen.	Vu states numerous advantageous features (related to employees, customers, and shareholders) from lean linked to business savings but were not quantified.
Brown, Eatock, Dixon, Meenan, & Anderson (2008)	The quality and continuous improvement strategies can be differentiated in terms of their cultural or process focus. TQM, Six Sigma, Lean production.	Study organizational factor for selecting a leadership style and a continuous improvement strategy focused on medical devices industrial sector but is only a brief literature-based review of a number of continuous improvement strategies. They do not validate it with case studies.
Grewal (2008)	VSM, Lean Manufacturing, SMED and WIP case study.	Merely focused on Lean Manufacturing, it does not contrast with other continuous improvement methodologies. It does not address economic implications.
Antony, Gijo & Childe (2012)	Six Sigma case study, including economic implications on business indicators. Apply regression analysis, hypothesis testing, Taguchi methods.	Focused on Six Sigma, it does not contrast with other continuous improvement methodologies. They present the savings but they do not detail the calculation.
Prashar (2016)	Introduce the simple and user friendly DoE tools into a well-established process improvement framework to enhance the effectiveness of Six Sigma projects.	Focused on Six Sigma, it does not contrast with other continuous improvement methodologies. It does not address economic implications on business indicators.
This case	Introduce the simple and user friendly PPI 8-step methodology, PDCA, Pareto and Ishikawa charts, ROI.	It could appear as a very plain approach.

on other indicators. Table 9 compares the different methodologies applied to implement continuous improvement in manufacturing industries, including research related to the medical devices manufacturing industry.

Vu (2007) and Grewal (2008) were focused on apply LM, specifically the tools VSM (Value Stream Map), OEE

(Overall Equipment Effectiveness), SMED (Single Minute Exchange of Die), Kaizen and WIP (Work in Process). In both cases, they do not contrast your choice with other options available for continuous improvement, and they do not economically quantify the impact of the improvement. Vu states numerous advantageous features (related to employees, customers, and shareholders) from lean linked to business savings but were not quantified.

Brown, Eatock, Dixon, Meenan, & Anderson (2008) study organizational factor for selecting a leadership style and a continuous improvement strategy focused on medical devices industrial sector but is only a brief literature-based review of a number of continuous improvement strategies. They do not validate it with case studies. Antony, Gijo & Childe (2012) and Prashar (2016) were focused on Six Sigma, they do not contrast with other continuous improvement methodologies. They present the savings but they do not detail the calculation.

This project does not present a problem of defective parts in the process, the problem is the waste of foil in the stamping process. This case study presents how a company can start with the implementation of continuous improvement, even without having a complex solving problems methodology such as Six Sigma or Lean Manufacturing implemented. PDSA-PDCA-based Practical Process Improvement is a viable alternative for resource-poor managers for their improvement programs. It can empower its employees for its use as part of its quality culture. In its analysis, this article considers that it is possible for companies to adopt different strategies to implement continuous improvement considering their resources, ranging from PPI, Lean Manufacturing and Six Sigma. Where PPI represents a simple and effective alternative to achieve significant improvements in processes.

VI. CONCLUSION AND FUTURE WORK

The PPI methodology allows companies to select priority issues to work on. Employees are formed into teams and solve important problems for the organization using the eight-step method. Then, leadership implements the solutions. Our case study confirms that PPI is a straightforward methodology that relies on the Deming Cycle (we substitute PDCA for PDSA according to [30], [31]).

Following the Pareto principle, the company decided to choose only the ink with the highest cost. Moreover, this study does not take into account all the products in which foil no. 9540 is used, since product no. 412 has the highest impact. Even though savings for this product reached \$124,445.87 USD at the end of the second phase, we estimate that total savings for foil part no. 9540 could reach up to \$165,000 USD, considering all the products that use this type of foil material.

It is important that companies sustain a simple improvement process, involve all stakeholders in said process, and apply practical and straightforward methods and tools that promote quick visible changes. PPI may not be viable for complex projects, since its value lies in its simplicity. Also, it is impossible to separate PPI from other improvement tools,

such as LM or SS, since they all share similar principles and knowledge bases. However, the difference between PPI and other improvement tools lies in the complexity of the goal that each of them pursue. This study confirms the usefulness and simplicity of PPI and demonstrates that it can bring significant economic benefits in the short term with well-focused efforts. In this case study, all this eventually translated into a short-term investment with quick capital recovery (i.e. less than a year in both phases of the project). Moreover, PPI is a dynamic methodology promoting immediate improvement events. Hence, when companies operate under a quality management culture, it is possible to make quick changes without much or no resistance from employees.

This project achieved a significant improvement from an economic perspective. However, it is currently necessary for continuous improvement projects to include indicators of environmental improvement and the impact on worker safety. As a next project related to this same work station, we propose an analysis of the environmental impact of the process due to the use of the pad printing machine, it is also possible to carry out a study on the effects of human-machine interaction on worker health.

DISCLOSURE STATEMENT

The authors declare no potential conflicts of interest with respect to the publication of this research.

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