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Integrating Statistical Process Control and Failure Mode and Effects Analysis to Reduce Product Defects in Oil Filter Manufacturing (Case Study: CV XYZ)

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ABSTRACT

CV XYZ is a small-to-medium-sized manufacturing company struggling with a high rate of product defects. This study integrates Statistical Process Control (SPC) and Failure Modes and Effects Analysis (FMEA) to analyze and improve the quality performance of the oil filter production process at CV XYZ. Several SPC tools were applied, including a check sheet, Pareto analysis, P-control chart, and root cause analysis using a fishbone diagram. The findings revealed that deformation was the most frequent defect type, accounting for 152 units (23%) out of 675 total defects recorded over five months. Root cause analysis identified multiple contributors to deformation defects, which were then evaluated using FMEA based on three parameters: severity, occurrence, and detection. The Risk Priority Number (RPN) calculations determined that excessive product stacking was the primary cause, followed by non-compliance with standard operating procedures (SOPs), a poorly organized workstation, and inadequate lighting and visibility. Based on these findings, several corrective actions were recommended, including improving SOPs for the pressing process, scheduling regular SOP training, and implementing standardized stacking procedures aligned with production output. These measures are projected to reduce total nonconformities by approximately 6.9%. The key contribution of this study is providing a practical quality improvement framework for SME manufacturers with limited quality management resources and analytical capabilities. The integrated SPC-FMEA approach enables data-driven decision-making without requiring extensive expertise. Nevertheless, real-world implementation remains necessary to validate the projected outcomes.

1. Introduction

Manufacturing companies are required to maintain competitiveness to ensure their long-term viability. One significant factor of a manufacturing company's success is the consistent production of high-quality products. Many manufacturing companies continue to encounter challenges related to non-conforming products and fulfilling customers' requirements. An effective quality control system must be established to enhance product quality and reduce production costs. From pre-production to the final inspection, manufacturing quality control encompasses a systematic and comprehensive strategy [1]. The objectives include maintaining the consistency of compliant products, enforcing adherence to established quality standards, and implementing corrective measures for deviations [2]. By identifying the root causes of product defects, quality control facilitates the production of outputs that meet predefined standards [3].

CV XYZ is a small to medium-sized manufacturing company based in Surabaya, specializing in the production and distribution of oil filter products. A major problem observed at CV XYZ is the high amount of defective products, which exhibit various types of product defects, including deformation, contaminated media, damaged mesh, peeling or corroded paint, and irregular adhesive application. The company's reputation and financial performance may suffer as a result of these issues, which also affect customer satisfaction. An effective implementation of the quality control process is crucial, since repeated product defects can cause long-term impacts to the company. Without an effective data-based quality control system, companies may face ongoing operational issues and incur financial losses. One effective method for overcoming the problem is the use of Statistical Process Control (SPC). SPC uses several statistical tools to help monitor, check, and improve quality in manufacturing companies [4]. Seven tools in SPC, including check sheets, histograms, control charts, Pareto charts, fishbone diagrams, scatter plots, and process flowcharts, have been proven helpful in identifying types of product defects and their root causes [1]. SPC can also work in conjunction with other tools, such as Failure Mode and Effects Analysis (FMEA). FMEA is a method used to identify potential failures and mitigate risks [6]. This method helps companies prioritize corrective actions by assessing risks based on three parameters: severity (the impact of a failure), occurrence (the likelihood of its recurrence), and detection (the probability of identifying the issue during processing) [7][8]. When combined with SPC, FMEA provides a risk-based approach to support decision-making.

Some previous studies have integrated SPC and FMEA along with other quality tools such as lean six-sigma and root-cause analysis (RCA), to improve the quality performance of manufacturing companies. Among others, [9] developed a predictive quality assurance model which integrates FMEA, SPC, and RCA under the lean six sigma framework. Furthermore, [10] integrated SPC and fuzzy-FMEA to reduce rejected products in the furniture industry. The study illustrated how SPC and fuzzy-FMEA can be applied to improve the product quality. In addition, a study by [11] also showed that the integration of SPC and FMEA can also be applied in a less-developed industry with are not mature enough.

Even though the integration of SPC and FMEA has been widely discussed in many quality management research, however, its application in small manufacturing companies remains limited. Also, there remains a limited number of studies that integrate SPC and FMEA into a unified, data-driven framework, particularly in small and medium-sized manufacturing industries. This study addresses this gap by integrating SPC and FMEA to help a small manufacturing company, CV XYZ, control and improve the quality of the oil filter production process. In this study, SPC is employed to objectively identify critical product defects and process instabilities, and FMEA is subsequently used to evaluate and prioritize the root causes based on risk levels. This integrated approach provides a more comprehensive and systematic basis for quality improvement decision-making compared to the standalone application of either method.

The objective of this study is to identify the most critical quality aspects, types of product defects, highlight the most common issues, understand the root causes, and suggest a practical action plan for improvement in the oil filter production process. The results are expected to help CV XYZ reduce product defects, improve quality, minimize production losses, and enhance customer satisfaction. This study also demonstrates how FMEA and SPC can be utilized together as effective tools for quality control, particularly in small to medium-sized manufacturing companies.

2. Methods

2.1. Research Methodology

In this study, the authors applied both qualitative and quantitative approaches to explore quality issues and recommend improvements by integrating SPC and FMEA methods. Figure 1 depicts the flowchart of the research methodology conducted in this study. Field observations were carried out to identify problems in the oil filter manufacturing process at CV XYZ. These were followed by data collection, analysis, and interpretation to support the findings. The SPC and FMEA methods were selected due to their applicability to solving quality problems. These methods are also considered effective in identifying the underlying causes and root causes of product defects, thereby providing practical improvements. The detailed methods used in this study, including the data and respondents, are described in the following subsections.

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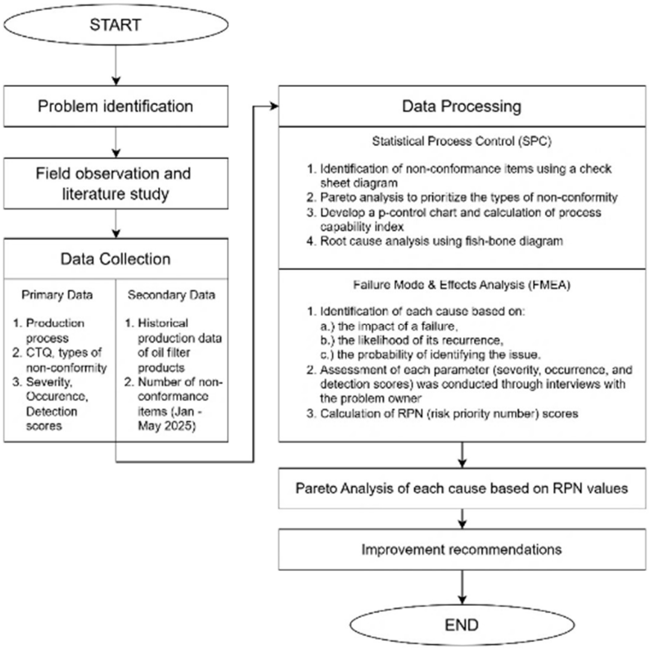

Figure 1. Research methodology

Table 1. Quality Characteristics and Defect Types of Oil Filter Products at CV XYZ

Production Stages	Quality Characteristics	Critical Specifications	Impact on Product	Type of product defects
Adhesive application and assembly	1. Glueing neatness 2. Glue strength	1. Glue must be evenly distributed 2. Must not be lumpy 3. Quantity must be appropriate	1. Glue does not adhere firmly 2. The product becomes easily damaged 3. Final assembly lacks precision and consistency	Irregular adhesive application
Preparation of Dacron media	1. Cleanliness of dacron filter media 2. Dacron condition is good	1. Dacron is free from dust or dirt 2. Worker's hands are clean 3. Dacron media storage must be clean	1. Potential clogging 2. Oil contamination	Contaminated Dacron media
Mesh installation and inspection (assembly)	1. Cutting size 2. Cutting quality 3. Hole size consistency	1. No tear 2. Precision smooth cut 3. All holes must meet standardized dimensions uniformly	1. Misalignment during assembly 2. Filtration leakage 3. Potential for functional failure in filtering	Damaged mesh
Filter body painting	1. Use the appropriate paint type 2. Apply using proper tools and techniques 3. Paint must be smooth, without blotches 4. Evenly distributed on the entire surface	1. The paint must adhere evenly 2. No peeling 3. Painting technique	1. Uneven or peeling paint 2. Susceptibility to corrosion 3. Reduced aesthetic and product selling value	Peeling or corroded paint

Production Stages	Quality Characteristics	Critical Specifications	Impact on Product	Type of product defects
Pressing process, final assembly, and packaging	1. Case dimensions (diameter, height) 2. Surface flatness 3. Symmetrical geometry shape	1. No dent 2. Even circumference 3. Proportional dimensions 4. Symmetrical case fit	1. Difficulty during assembly 2. Potential leakage during operation 3. Reduced product reputation due to visible physical defects	Deformation

2.2. Data Collection

The data used in this study consists of two types: primary data and secondary data. Primary data were collected through direct observation at CV XYZ. These include data on oil filter production volume, types and quantities of product defects, production process flow, and RPN values calculated using the FMEA method. In addition, the authors utilized primary data obtained through interviews with 3 key decision-makers, including the business owner, the production manager, and the production supervisor of CV XYZ.

Secondary data were obtained from company documents and production records from the last five months. In addition, literature and references relevant to the research topic were used to support the analysis. The historical defect data from January to May 2025 became the primary reference in this study. During this period, five types of product defects were found: deformation, contaminated dacron media, damaged mesh, peeling or corroded paint, and irregular adhesive application. Table 1 shows the quality characteristics and defect types of oil filter products at CV XYZ.

2.3. Integration Framework of SPC and FMEA

This study uses SPC and FMEA as an integrated methodology to overcome problems related to product defects. SPC is used to identify statistically dominant defects, while FMEA prioritizes corrective actions based on associated failure risks. In this framework, SPC serves as the quantitative screening stage, while FMEA functions as the decision-support stage for prioritizing improvement actions. These two methods are integrated through output-input dependency, where the outputs of SPC are used as inputs in FMEA. The integration framework is depicted in Figure 2.

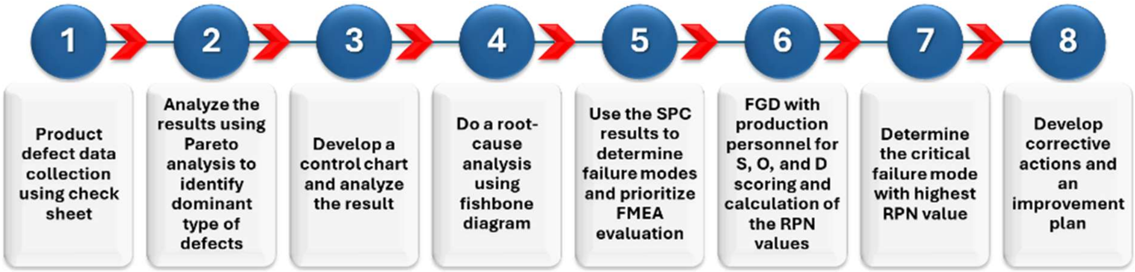

Figure 2. The SPC-FMEA integration framework was used in this study.

The contribution of this study mainly lies in demonstrating a practical integration of SPC and FMEA for quality improvement in an SMEs (small and medium enterprises) manufacturing environment. Unlike large companies, SMEs require a simpler and more practical implementation framework. The proposed framework enables SMEs to transform routine defect monitoring into structured risk prioritization and corrective action planning.

3. Results and Discussions

3.1. Statistical Process Control (SPC)

a. Check Sheet

Data collection is based on observations and historical data for the period from January to May 2025, as shown in Table 2.

Table 2. Total Production and Defect Data January - May 2025

Month	**Total Production (units)**	**Types of Product Defects**					
		Deformation (units)	**Contaminated Dacron Media (units)**	**Damaged Mesh (units)**	**Peeling or Corroded Paint (units)**	**Irregular Adhesive Application (units)**	**Total Product Defects (units)**
Jan 2025	500	35	25	40	31	24	155
Feb 2025	445	52	20	33	29	36	170
Mar 2025	600	23	35	27	41	20	146
Apr 2025	400	20	15	30	12	17	94
May 2025	530	22	23	14	29	22	110
Total	**2475**	**152**	**118**	**144**	**142**	**119**	**675**

b. Pareto Analysis

Based on the product defects data compiled using the check sheet, a Pareto diagram analysis was conducted to identify the most frequently occurring types of product defects. Table 3 presents the cumulative percentage of the five types of product defects identified in the oil filter production process during the period from January to May 2025.

Table 3. Calculation of the Cumulative Percentage of the Five Types of Product Defects

No.	**Type of Product Defects**	**Number of Product Defects (units)**	**Cumulative Number (units)**	**Percentage**	**Cumulative Percentage**
1.	Deformation	152	152	23%	23%
2.	Damaged Mesh	144	296	21%	44%
3.	Peeling or corroded paint	142	438	21%	65%
4.	Irregular adhesive application	119	557	18%	83%
5.	Contaminated dacron media	118	675	17%	100%
	Total	**675**		**100%**	

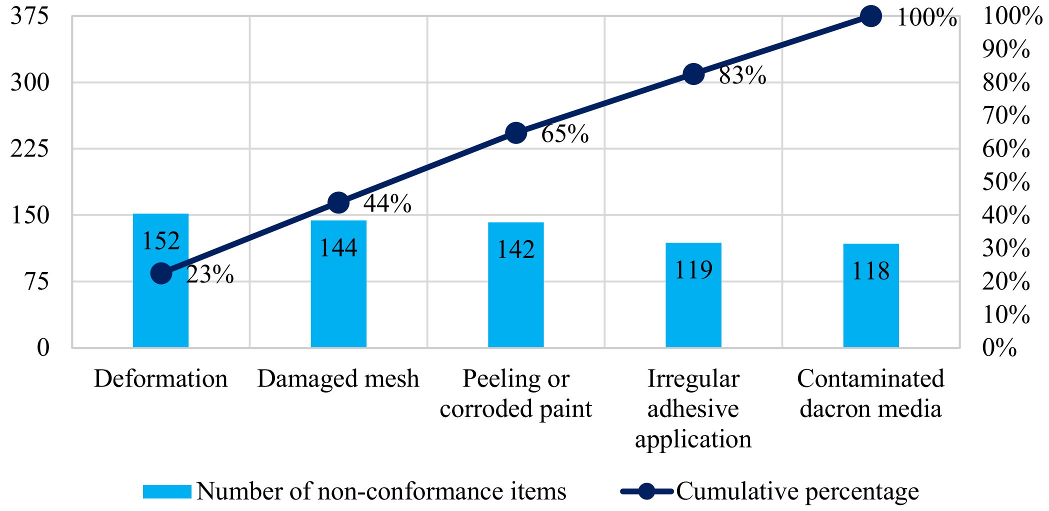

Figure 3. Pareto Diagram of Five Product Defects in Oil Filter Products.

Table 3 shows that the most frequent type of product defects, accounting for 23% of the total, is 152 defective units. In contrast, contaminated Dacron media represents the lowest proportion at 17%, with 118 defective units. The distribution of the five types of product defects is illustrated in the Pareto diagram in Figure 3. The Pareto principle, also known as the 80/20 rule, states that 20% of quality problems are caused by 80% of the defect types. Based on Figure 3, the results indicate that deformation defects are considered the top priority or problem statement in the pressing process, which warrants further study. Therefore, it can provide an improvement plan that significantly reduces the types of defects that occur.

c. Control Chart

A P-control chart (P-Chart) offers several benefits that help control production quality and provide information about when and where the company should implement quality improvements. It can be said that variability does not occur in significant deviations from predetermined standards or specifications. The steps for developing a P-Chart are as follows, as an example of calculation for the type of deformation defect that occurred in January:

i. Calculation of the proportion of product defects

$$p = \frac{np}{n} = \frac{35}{500} = 0.070 \tag{1}$$

with np = number of product defects and n = average sample quantity/inspection level.

ii. Calculation of the center line ($\bar{p}$)

$$\text{CL} = \bar{p} = \frac{\sum np}{\sum n} = \frac{152}{2{,}475} = 0.061 \tag{2}$$

with $CL = \bar{p}$ center line, $\sum np$ = total number of product defects and $\sum n$ = total number of production/inspected items.

iii. Calculation of the Upper Control Limit (UCL)

$$\text{UCL} = \bar{p} + 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}} = 0{,}061 + 3\sqrt{\frac{0{,}061\ (1-0{,}061)}{500}} = 0.094 \tag{3}$$

with $\bar{p}$ = center line/proportion of product defect and n = average sample quantity/inspection level.

iv. Lower Control Limit (LCL)

$$\text{LCL} = \bar{p} - 3\sqrt{\frac{\bar{p}(1-\bar{p})}{n}} = 0{,}\bar{0}61 - 3\sqrt{\frac{0{,}061\ (1-0{,}061)}{500}} = 0.029 \tag{4}$$

Table 4 summarizes the results of the P-chart on the type of deformation defect from each period. Consequently, the graphical plot of the corresponding P-chart is depicted in Figure 4.

Table 4. P-chart Calculation Results for the Deformation Type of Product Defects

Month	Production Quantity (units)	Deformed items (units)	p	CL ($\bar{p}$)	UCL	LCL
January	500	35	0.070	0.061	0.094	0.029
February	445	52	0.117	0.061	0.096	0.027
March	600	23	0.038	0.061	0.091	0.032
April	400	20	0.050	0.061	0.097	0.025
May	530	22	0.042	0.061	0.093	0.030
Total Quantity	**2475**	**152**				

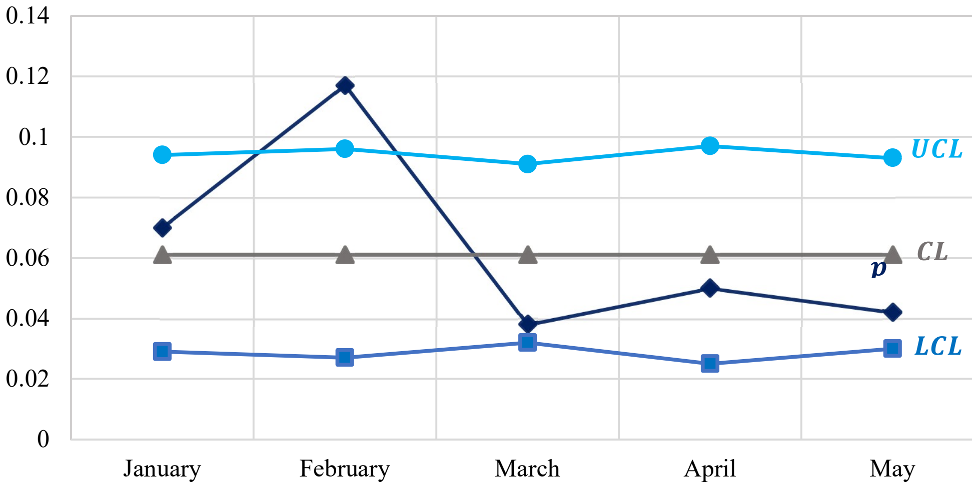

Figure 4. P-Chart of Deformation Type of Product Defects.

Based on Figure 4, the monthly proportion of product defects is presented with an average defect proportion, or center line (CL), of 0.061. The control chart also displays varying upper control limits (UCL) and lower control limits (LCL). The point representing February exceeded the upper control limit, indicating a special cause variation according to Rule 1. A deeper investigation of production logs revealed that during this period, Machine A experienced an unplanned stoppage, and operators temporarily used a backup mold, which was later found to have dimensional wear. This operational disturbance explains the increase in product defects for February, as reflected in the SPC chart.

To further understand the variation in process performance, an exploratory capability analysis was conducted using the monthly defect proportions during the observation period (January to May 2025). To calculate the process capability values (Cp and Cpk), the standard deviation of defect proportion (σ_p) needs to be calculated first

$$\sigma_p = \sqrt{\frac{\sum(x_i - \bar{x})^2}{n-1}} = \sqrt{\frac{0.0041992}{5-1}} = 0.0324 \qquad (5)$$

Using the specification limits of LSL=5%, average SL=5%, and USL=15%, the calculated Cp and Cpk values are given as follows.

$$Cp = \frac{USL-LSL}{6\sigma} = \frac{15\%-5\%}{6(0.0324)} \approx 0.51 \qquad (6)$$

$$Cpk = \min\left\{\frac{USL-SL}{3\sigma}, \frac{SL-L}{3\sigma}\right\} = \min\left\{\frac{15\%-10\%}{3(0.0324)}, \frac{10\%-5\%}{3(0.0324)}\right\} = \min\{0.39, 0.14\} = 0.14 \qquad (7)$$

The calculated values for process capability were $Cp = 0.51$ and $Cpk = 0.14$. The Cp value indicates that the variation in the defect proportion is still relatively high compared to the acceptable range, meaning that the process is not yet capable of consistently achieving the expected quality level. The lower Cpk value also suggests that the process was not stable across the observation period and was affected by fluctuations in defect occurrence. This result aligns with the SPC findings, which showed special cause variation, especially in February 2025 when the defect proportion exceeded the control limit. These findings support the need for improvement actions focused on reducing process variation and addressing the main causes of deformation identified through the root-cause analysis and FMEA.

d. Root-cause Analysis using the Fishbone Diagram

After identifying the quality issues, the next step involves analyzing the underlying factors contributing to deformation defects. A fishbone diagram is utilized to systematically identify and examine the causal relationships and key factors influencing the decline in the quality of oil filter products. Figure 5 illustrates the fishbone diagram used to analyze the potential root causes of deformation.

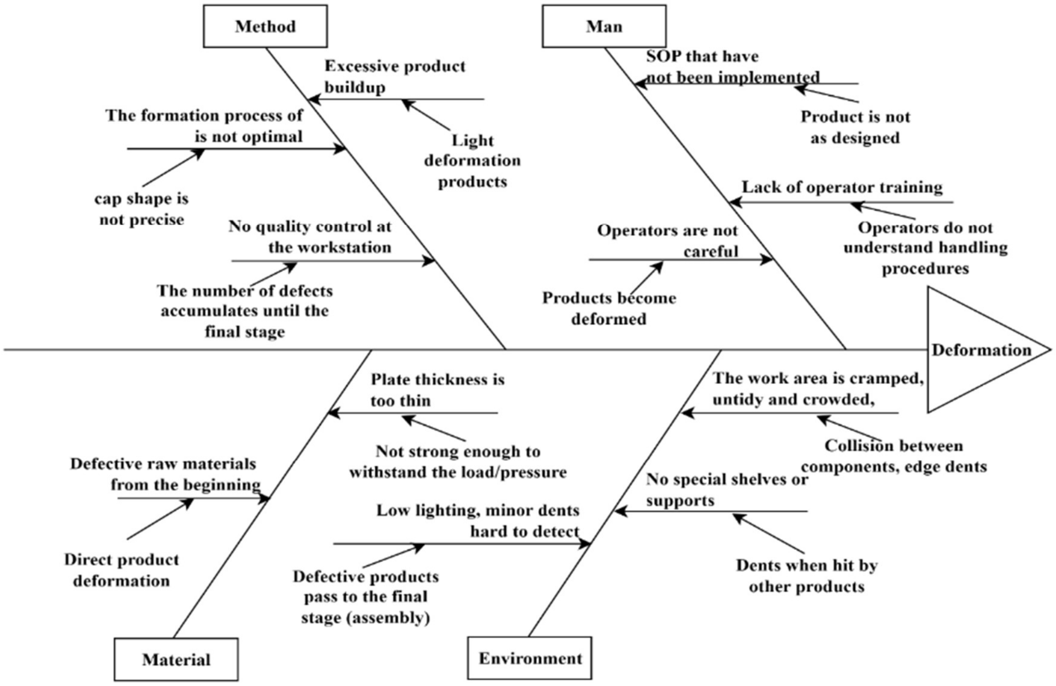

Figure 5. Fishbone Diagram of Deformation Defect Types

Table 5. FMEA Analysis and RPN Value

Potential Failure Mode	Factor	Potential Effect of Failure	(S)	Cause of Failure	(O)	Current Process Control	(D)	RPN
Deformation	Man	Products produced do not match the design	8	SOPs that have not been implemented	9	No established routine for reinforcing SOPs in the pressing process	8	576
		Operators do not understand handling procedures	5	Lack of operator training	7	No intensive training program	9	315
		Products become deformed during handling	7	Lack of careful handling by operators	8	No direct supervisor or double-check system	8	448
	Method	The product becomes uneven or shows mild deformation	8	Excessive product stacking	9	No standard stacking procedures or arrangements	9	648
		The shape of the top and bottom lids is not precise	7	The forming process is not optimal	7	High-speed press process stages	8	392
		The number of defects accumulates until the final stage	8	There is no quality control at the press stage workstation	6	Inspection only at the end of the entire production process (assembly)	9	432
	Material	Not strong enough to withstand the load	8	The thickness of the plate is too thin	5	Visual inspection without any measuring tools	6	240

Potential Failure Mode	Factor	Potential Effect of Failure	(S)	Cause of Failure	(O)	Current Process Control	(D)	RPN
		The product is immediately deformed from the beginning of the process	4	Raw materials are defective from the start	4	No standard procedure for checking incoming material damage	7	112
	Environ-mental	Collision between components, dents on the side	6	The work area is narrow, untidy, and crowded	10	No supervision of layout or inefficient product movement flow	9	540
		The shape of the press results changes, dents when hit by other products	6	There are no special shelves or supports	10	Products are placed directly on the floor or plants in cardboard boxes	8	480
		Defective products pass to the final stage (assembly)	9	Minimal lighting, and minor dents are difficult to detect	7	No additional visual inspection with lighting aids	8	504

3.2. Failure Mode and Effect Analysis (FMEA)

Based on the results of the SPC analysis conducted previously, the findings serve as the basis for constructing the Failure Mode and Effects Analysis (FMEA) table. The FMEA scoring system is explicitly defined using a standardized 1–10 scale for Severity (S), Occurrence (O), and Detection (D). The assessment was done by the three production personnel. Occurrence values are determined based on historical defect data and SPC results, while Severity and Detection are assigned according to failure impact and existing inspection practices at CV XYZ. The Risk Priority Number (RPN) is calculated as the product of S, O, and D to objectively prioritize improvement actions and minimize subjectivity. The FMEA results based on the assessment from the 3 key decision-makers, which include the business owner, the production manager, and the production supervisor of CV XYZ, are given in Table 5.

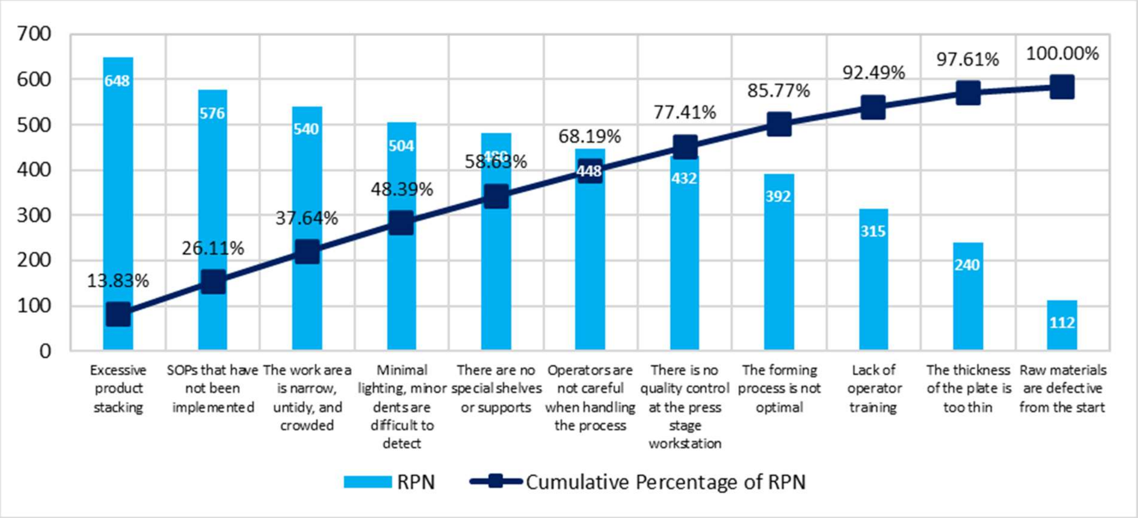

Figure 6. Pareto Diagram RPN Value

Based on the Pareto diagram in Figure 6, the highest RPN value is associated with "excessive product stacking," categorized under the method factor (A), with an RPN of 648 and a cumulative percentage of 14%. This is followed by "ineffective implementation of SOPs," identified under the human factor (B), with an RPN of 576 and a cumulative percentage of 26%. These findings suggest the need for improvement initiatives that target both factors.

3.3. Corrective Actions and Expected Quality Improvement

The proposed corrective actions for improvement are presented in Table 6.

Table 6. The Proposed Deformation Defect Action Plan for Improvement

Type of Product Defects	Factor	Potential Effect of Failure	Causes with Highest RPN	Action Plan for Improvement
Deformation	Man	Products produced do not match the design	SOPs that have not been implemented	1. Revise and redevelop the SOP for the pressing stage, and ensure consistent operator awareness through periodic training sessions and visual displays of the SOP in the work area. 2. Conduct regular internal audits to verify disciplined implementation of the SOPs.
	Method	The product becomes uneven or shows mild deformation	Excessive product stacking	1. Redesign the work area layout to separate the products from the pressing process. 2. Provide multilevel storage racks so that products are not excessively stacked and do not bump into each other. 3. Develop a standard procedure for maximum stacking based on the amount produced.

Based on the SPC results, deformation defects represented approximately 23% of total product defects, with an average monthly defect rate of 11.7%. The proposed improvements, elimination of excessive product stacking and SOP reinforcement, directly address the highest RPN failure modes (RPN = 648 and 576). Since the proposed improvement plan in Table 6 was not implemented during the study period, the expected improvement outcome was estimated based on expert evaluation involving production personnel, as well as assessment of the identified respective failure causes from FMEA. A conservative estimate suggests a 30% reduction in deformation defects (detailed estimation can be seen in Table 7). Administrative controls (redeveloped SOP, training, and audits) were expected to improve process consistency and reduce operator-related variation, while physical interventions (layout redesign and storage racking-system improvement) were expected to reduce product deformation caused by improper handling and excessive stacking.

Table 7. Calculation of the Expected Defect Rate Reduction from the Proposed Improvement Plan based on Production Personnel Evaluation

No.	Proposed Action Plan for Improvement	Target Failure Mode	Expected Reduction
1.	Redeveloped SOP and operator training	Deformation	10%
2.	Internal audits for SOP compliance	Deformation	5%
3.	Redesign work area layout	Deformation	5%
4.	Multilevel storage racks and controlled stacking procedure	Deformation	10%
	Total estimated reduction		**30%**

From the initial deformation defect rate, which is 23% (see Figure 2), the estimated overall reduction in total defects can be calculated as follows.

$$\%\ \textit{estimation of overall defect reduction} = \textit{initial defect rate of deformation} \times \textit{estimated reduction}$$
$$= 23\% \times 30\% = 6.9\% \qquad (8)$$

Given that deformation defects accounted for approximately 23% of total defects, the proposed reduction corresponds to an estimated overall decrease of approximately 6.9%. However, this estimation should be interpreted as projected improvement potential and requires future validation through implementation and post-improvement measurement.

The required implementation costs of the proposed improvement plan are relatively low and mainly preventive, covering training, documentation, layout redesign, and storage racking system improvement. In contrast, the benefits include reduced scrap and rework, improved process stability, and lower risk of special cause variation. These results indicate a favorable cost-benefit ratio and support the economic feasibility of the proposed improvements.

4. Conclusion

Based on the results of the Statistical Process Control (SPC) analysis, the oil filter production process at CV XYZ is still not statistically stable. This instability is especially visible in February and May 2025, showing that special cause variations occurred. During the five months, there were 675 non-conforming products recorded. The highest, most frequent issue was deformation, with 152 cases or around 23% of all defects. These numbers were collected using check sheets that tracked weekly data on types and amounts of product defects. The fishbone diagram showed that the main causes of deformation came from four areas: human, method, material, and environment. Based on Table 4, the proportion of deformation defects in February ($p = 0.117$) exceeded the Upper Control Limit ($UCL = 0.096$), indicating a special cause variation, while the other months remained within control limits. Production records show that this anomaly coincided with an unplanned stoppage of Machine A, which led to the temporary use of a backup mold with dimensional wear. The use of non-standard equipment without prior validation disrupted the pressing process and increased deformation defects, the dominant product defects identified by Pareto analysis. This condition is consistent with the FMEA results in Table 5, where pressing-related methods and human factors received high Occurrence and Detection scores, resulting in elevated RPN values. These findings confirm that the February deviation was caused by assignable factors rather than common process variability.

Further analysis using the Failure Mode and Effects Analysis (FMEA) method provided several suggestions for improvement. For the human factor, which had the highest Risk Priority Number (RPN), the recommended action is to revise and redistribute the SOP for the pressing stage. This should be followed by regular operator training and visual displays of the SOP in the work area, as well as routine internal audits to ensure proper adherence. For the method factor, proposed improvements include redesigning the work area layout to separate pressed products, adding multi-tier storage racks to avoid product stacking, and setting a clear standard for the maximum number of stacked units based on output. The proposed improvements were prioritized based on the FMEA results and targeted the dominant causes contributing to deformation defects identified through SPC analysis. Based on expert assessment, the proposed improvements are projected to reduce total defects by approximately 6.9%. Nevertheless, this should be interpreted as an estimated value for potential improvement and requires validation through actual implementation. Therefore, future research is recommended to extend the observation period, include a more diverse range of defect types, and validate the proposed improvements through longitudinal analyses or before-and-after implementation comparisons. The integration of complementary methods such as Design of Experiments (DOE) or Six Sigma also has the potential to enhance process optimization and the generalizability of the results.

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