Efficiency Improvement in a Recycled Cardboard Crate Production Line Using SMED 4.0, Taguchi Methods, and Digital Twin Technology

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***Abstract*- The project proposes an integrated continuous improvement model that combines engineering tools and Industry 4.0 technologies to optimize efficiency and reduce defects in a recycled paper tray production line. The study addresses a common problem in the manufacturing sector: the high rate of non-conforming products, excessive unscheduled downtime, and long changeover times. The proposed model integrates the SMED 4.0 methodology, the Taguchi Method, and the Digital Twin Digital Tool, focusing on reducing setup time, optimizing critical parameters, and predictive process monitoring. The research was conducted through digital simulation and experimentation, validating its effectiveness with quantitative performance indicators. The results demonstrated a reduction in the defective product rate from 10.28% to 2%, a decrease in unscheduled downtime from 21 to 7 events per month, and a reduction in changeover time from 24 h to 14.4 h per month, meeting established efficiency standards. This model offers a scalable and replicable solution for industrial SMEs seeking to advance toward Industry 4.0 through accessible technologies and proven engineering methodologies.**

Keywords: Non-conforming products; Lean Manufacturing; Design of Experiments; Industry 4.0; Rework; Continuous Improvement.

I. Introduction

The recycled paper packaging manufacturing industry is a strategic sector in Peru and Latin America, supporting the poultry supply chain through the production of egg transport trays [1]. In Peru, manufacturing contributes approximately 13% of the Gross Domestic Product (GDP), with an annual growth rate of 3.3% [2]. However, small and medium-sized enterprises (SMEs) continue to face limited digitalization and automation capabilities, reducing their operational efficiency and competitiveness [3].

Lean Manufacturing combined with Industry 4.0 technologies has demonstrated improvements in industrial performance through tools such as value stream mapping, autonomous maintenance, and IoT monitoring, achieving efficiency gains of 10%–20% and waste reduction [4], [5]. Nevertheless, these approaches are generally designed for technologically mature industries, limiting their applicability to resource-constrained SMEs. In Peru, more than 60% of industrial SMEs remain at a basic level of digital maturity, lacking automated control and real-time monitoring systems [3].

This research addresses these challenges by proposing an integrated improvement model for a Peruvian recycled paper tray manufacturing plant with 15% molding line inefficiency, a 10.28% defect rate, and changeover times exceeding 24 hours. The model combines SMED 4.0 to reduce setup times, the Taguchi method to optimize process parameters, and a Digital Twin for predictive monitoring and control. This hybrid approach promotes a gradual and cost-effective transition toward Industry 4.0 while supporting operational excellence and productive modernization strategies in traditional manufacturing sectors [6].

II. State of Art

The state-of-the-art review identified a growing integration of Lean Manufacturing and Industry 4.0 technologies to optimize industrial processes. This hybrid approach combines continuous improvement tools with intelligent monitoring and data analysis, enhancing productivity, traceability, and quality in manufacturing environments [7], [8].

A. Applications of the SMED 4.0 method

The SMED (Single-Minute Exchange of Die) method is widely recognized for reducing changeover times and improving production flexibility. Applications in manufacturing industries have reported downtime reductions of up to 60% through activity separation, tool redesign, and procedure standardization [9], [10]. Its evolution toward SMED 4.0 integrates IoT sensors, artificial intelligence, and data analytics to automate changeover monitoring, enabling the identification of hidden inefficiencies and supporting continuous improvement with quantitative evidence [11] – [13].

Additionally, process simulation enables the evaluation of changeover scenarios without disrupting production, reducing configuration risks and operational losses [14]. In low-digitalization environments, SMED supported by electronic records has achieved downtime reductions of up to 50% within six months [11]. However, its effectiveness depends on technological maturity and real-time data management capabilities, making gradual implementation with digital records and performance dashboards the most suitable approach.

B. Applications of the Taguchi Method in parameter control

The Taguchi method is a robust statistical technique for optimizing industrial process parameters through orthogonal designs, reducing variability with a limited number of experiments [15]. In manufacturing, it has been successfully applied to molding, casting, and welding processes, achieving defect reductions of more than 70% by optimizing operating conditions [16]. In the recycled paper industry, it has also improved compaction and reduced product deformation [17].

Recent studies highlight its integration with response surface analysis and digital simulation, enabling more accurate predictive models and virtual experimentation without interrupting production [18] – [20]. Combined with predictive models, this approach supports quality improvement while reducing implementation costs, making the Taguchi method an effective link between conventional manufacturing and Industry 4.0 technologies [21].

C. The usage of Digital Twin in manufacturing and quality control

The Digital Twin has become a key technology for manufacturing digitalization by creating virtual replicas synchronized with physical systems for real-time monitoring, simulation, and predictive control [22]. Its implementation has improved decision-making, process traceability, and operational efficiency.

Applications in molding and assembly lines have achieved up to 95% accuracy in defect detection and enabled automatic parameter adjustment to prevent non-conforming products [23], [24]. In Latin America, low-cost solutions based on sensors, microcontrollers, and open-source software have facilitated the adoption of Digital Twin technologies in SMEs, supporting remote monitoring, digital Poka Yoke, and gradual digital transformation without major infrastructure investments [25]. Additionally, Digital Twins contribute to sustainability by optimizing energy consumption and predicting equipment wear [26].

Conceptually, the Digital Twin and Poka Yoke 4.0 represent complementary but distinct functionalities within an Industry 4.0 quality-control architecture. The Digital Twin provides the virtual representation and data-driven environment required to monitor, simulate, and analyze the behavior of the physical process, whereas Poka Yoke 4.0 refers to the error-prevention and deviation-detection logic implemented through digital technologies. Accordingly, in this study, the Digital Twin is not considered synonymous with Poka Yoke 4.0; rather, it constitutes the digital infrastructure through which process conditions can be continuously monitored and predefined rules or predictive models can generate alerts when deviations from validated operating conditions are detected. This distinction is essential to understand the proposed integration between statistical parameter optimization and digital error prevention [21].

D. The usage of Lean Manufacturing tools in Industry 4.0

Recent research has increasingly integrated Lean Manufacturing with Industry 4.0 technologies, creating hybrid models that combine operational efficiency with data-driven decision-making [28], [29]. These approaches have reported overall efficiency improvements of 15%–25%, along with reductions in defects and downtime [30]. However, most applications focus on highly automated industries, limiting their applicability to low-digitalization environments.

The literature identifies three main gaps: the predominance of automation-oriented models over statistical optimization, the lack of integrated frameworks combining SMED, Taguchi, and Digital Twin, and the limited evidence from Latin American SMEs using accessible digital technologies. To address these limitations, this study proposes an integrated improvement model that combines SMED 4.0, the Taguchi method, and Digital Twin for a recycled paper tray production line. The proposed approach promotes a gradual, measurable, and sustainable digital transformation using accessible industrial engineering tools.

III. CONTRIBUTION

The proposed model (Fig. 1) optimizes efficiency and quality in a recycled paper tray production line by integrating Industry 4.0 technologies with continuous improvement methodologies. It comprises two complementary phases: Phase 1, which combines the Taguchi method and Poka Yoke 4.0 to optimize quality, and Phase 2, which applies SMED 4.0 to reduce downtime.

A. Phase I

Component 1 – Taguchi Method

This component aims to reduce defective products by optimizing process parameters. As shown in Fig. 2, it begins with the formation of a team to design and execute controlled experiments, followed by the definition of the process factors and output variables. In this study, the evaluated factors are speed (1000, 1200, and 1400 rev/min), pressure (0.4, 0.6, and 0.8 MPa), and temperature (180, 200, and 220 °C), each with three levels for the Taguchi experimental design.

Likewise, the output variable is decided, which represents the characteristic to be minimized; in this case, it is the number of defective products. Therefore, our objective is to minimize said defects. After establishing the values and objective, the sample size of the experiments is calculated. For this, the following formula is used, which resulted in 145 crates.

$$n = \frac{N \times Z_{\alpha}^{2} \times p \times q}{e^{2} \times (N-1) + Z_{\alpha}^{2} \times p \times q} = \frac{2\,893\,353 \times 1.96_{\alpha}^{2} \times 0.035 \times 0.965}{0.03^{2} \times (2\,893\,353 - 1) + 1.96_{\alpha}^{2} \times 0.035 \times 0.965} = 145 \ \textit{jabas}$$

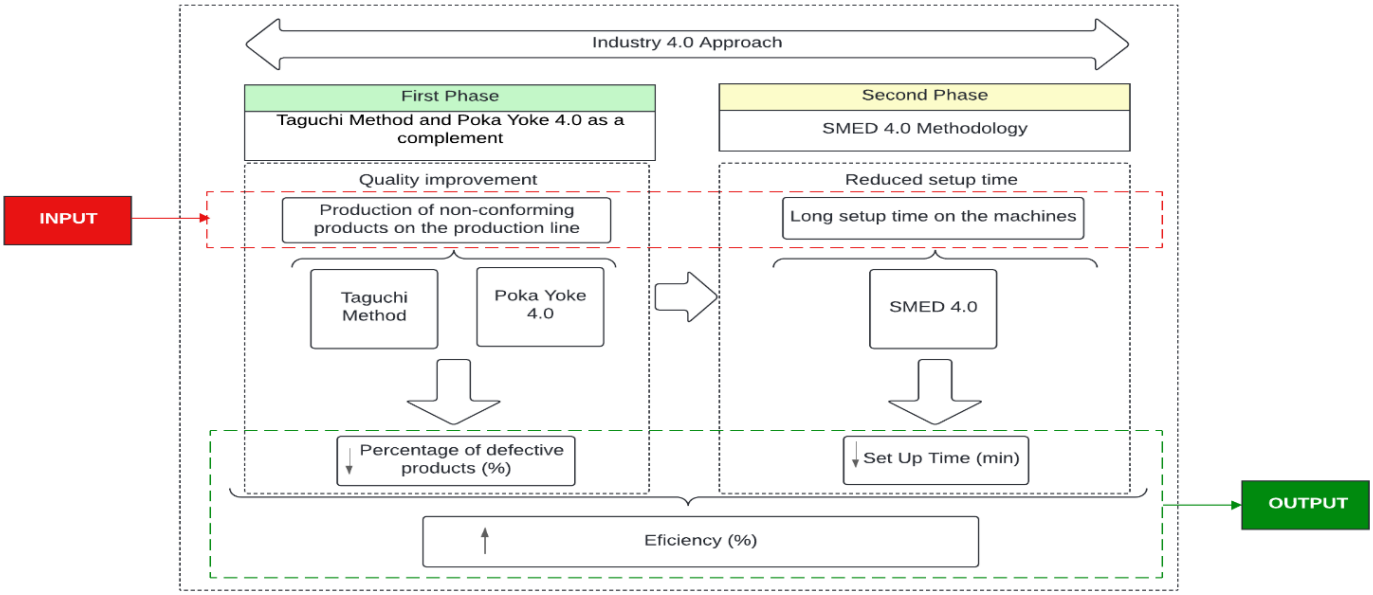


Fig. 1 Proposed Solution Model

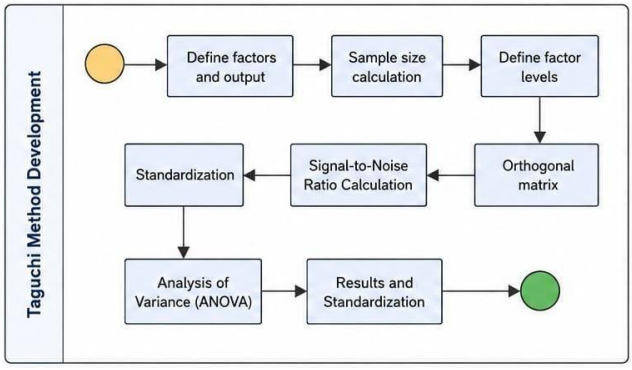


Fig. 2 Taguchi Method Workflow

With the previously calculated and established data, the Taguchi orthogonal matrix that best fits the number of factors and levels is selected. This matrix is the L9 matrix, which contains 9 combinations of the values shown (See Table I).

TABLE I
ORTOGONAL MATRIX L9

Combination	Speed (RPM)	Pressure (MPa)	Temperature (°C)
1	1,000	0.4	180
2	1,000	0.6	200
3	1,000	0.8	220
4	1,200	0.4	180
5	1,200	0.6	200
6	1,200	0.8	220
7	1,400	0.4	180
8	1,400	0.6	200
9	1,400	0.8	220

The sample n calculated above represents the quantity of crates to be produced in each combination to ensure optimal results for the experiment. To implement this production, three repetitions of 48-48-49 units will be carried out, each in one of the company's three daily shifts. Based on the experimental tests, the results are averaged to obtain an output value per combination. Ideally, the standard is 3.5% for defective products.

From these results, the Signal-to-Noise (S/N) ratio is calculated, which aims to minimize defects. The established objective is taken into account when choosing which type of S/N to use; therefore, the smaller the S/N, the better. While this calculation can be performed manually, the information will be processed using Minitab, which provides the results more easily.

The higher the S/N value, the better the performance and the lower the variability. Therefore, the values obtained are averaged for each factor level. From this, the values of the most suitable factor for reducing defective products are obtained (See Table II).

TABLE II
S/N RATIO RESULTS

Factor	Level 1	Level 2	Level 3	Best Level
Speed	18.2	20.5	21.0	3
Pressure	19.8	20.7	19.2	2
Temperature	18.9	21.3	19.5	2

An ANOVA (analysis of variance) in Table III, is then applied to determine which factors have the greatest influence on process variability. This analysis is performed using Minitab software.

TABLE III
ANOVA RESULTS

Factor	SS	GL	MC	F	Impact (%)
Speed	40.5	2	20.25	6.75	32.4%
Pressure	62.0	2	31.00	10.34	49.6%
Temperature	15.6	2	7.80	2.60	12.5%
Error	6.0	2	3.00	-	5.5%
Total	124.1	8	-	-	100%

It can be seen that pressure had the greatest impact (49.6%), followed by speed (32.3%), and finally temperature (12.5%). The optimal values were 0.8 MPa, 1200 rpm, and 200 °C, respectively.

Component 2 – Digital Twin-enabled Poka Yoke 4.0

After obtaining the optimal process parameters through the Taguchi method, the Digital Twin was incorporated as the digital monitoring and analysis layer of the proposed Poka Yoke 4.0 mechanism, with those necessaries' steps:

- Physical Process
- Sensors / PLC
- Data Acquisition
- Digital Twin: real-time representation, data integration, simulation and anomaly analysis.
- Poka Yoke 4.0 Logic: predefined limits, deviation detection, predictive models and alerts.
- Operator / Process Response

In this architecture, the Digital Twin provides a virtual representation of the molding process by integrating real-time data from the physical system, while the Poka Yoke 4.0 layer uses predefined process limits, rules, and predictive models to detect deviations and generate alerts before they result in non-conforming products. Therefore, the Digital Twin and Poka Yoke 4.0 are considered complementary components rather than equivalent technologies. The former enables continuous process representation, monitoring, simulation, and analysis; the latter operationalizes this information for digital error prevention and early deviation detection.

To implement the tool, a preliminary design must first be created to define the desired monitoring points and variables to be considered, select appropriate sensors, and validate compatibility. After this planning, the sensors and PLC are installed. This includes the necessary wiring and connections, as well as the installation of the Edge Gateway, a software that acts as an intermediary between devices and networks and processes data close to where it is generated. The process continues with the configuration of the network and local system, which establishes a reliable data network. This consists of creating a local Ethernet network between the PLC, Gateway, and server, as well as installing the Node-RED software, which is capable of creating acquisition nodes.

The data will also be stored in InfluxDB, and the necessary visualizations will be generated through Grafana. Based on the aforementioned, the Digital Twin model can be developed in the AWS IoT TwinMaker software.

The optimal parameter levels obtained from the Taguchi analysis are incorporated into the Digital Twin as reference operating conditions. These values establish the baseline against which real-time process data are continuously evaluated. When the monitored variables deviate from the defined operating ranges, the Poka Yoke 4.0 logic generates digital alerts and identifies potential error conditions. Consequently, the Digital Twin performs the functions of virtual representation, data integration, and process analysis, whereas the Poka Yoke 4.0 mechanism converts the resulting information into an error-prevention and early-warning function. This part of the application is where inefficiencies or anomalies can be identified.

Finally, algorithms are applied to optimize the process and generate improvements. The chosen algorithms are Active Learning (DNN) and Domain Adversarial Neural Networks (DAN). The former aims to reduce the amount of labeled data and train the system with fewer examples. The latter serves to generalize the model and make it applicable to different variable conditions. This set of rules makes up the part of the system that detects fault conditions in real time and predicts defects, as well as defines the system's adaptability. In the future, and optionally, they can be used for scaling and automation through integration with ERP, connection to the cloud, among others. The considerations for this tool are detailed in Table IV.

TABLE IV
CONSIDERATIONS FOR IMPLEMENTING DIGITAL TWIN

Consideration	Description
Human Resources	Formation of a work team for the implementation and monitoring of the tool.
Software	Node-RED, InfluxDB, Grafana, PyTorch, Siemens, IOT2040 (gateway), AWS IoT TwinMaker (Digital Twin Platform), AVEVA, Wonderware (SCADA).
Hardware	Siemens S7-1200 (PLC), Profinet (industrial network), Industrial Mini PC with GPU.
Infraestructure	Network connection and cabling.
Sensors	SICK TBS-1 (temperature), SMC ISE30A (pressure), OMRO incremental rotary encoder model E6B2-CWZ6C (speed)
Training	Intended for operators, technicians, and engineers who are already part of the company so they can understand the operation, application, benefits, and monitoring of this tool.
Implementation	Word, Excel, and physical notebook to keep records and notes regarding the implementation process and its results.

B. Phase II

Component 3 – SMED 4.0

The implementation of this proposed improvement methodology aims to reduce downtime caused by machine setup time in the production process. The steps for implementation are shown in the following Fig. 3.

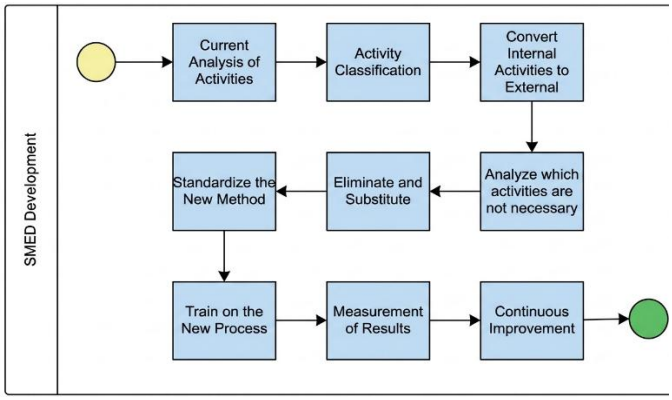


Fig. 3 SMED Application Flow

C. Indicators

Table V presents the indicators selected to evaluate the impact of the technical proposals on the production process. These indicators will monitor the achievement of the project's specific objectives, including reduced the defective product index, decreased unscheduled downtime and consequently improved efficiency.

TABLE V
MODEL INDICATORS

Indicator	As-Is	Target
Efficiency	89%	99%
Defective Product Index	10.28%	≤ 2%
Number of Unscheduled Stops due to Incorrect Parameters	21 per Month	≤ 7 per Month
Time of Change Over	24 Hours / Month	≤ 15 Hours / Month

IV. VALIDATION

The validation process is an essential step in verifying the effectiveness of the proposed model. An experimental-computational approach was applied, combining digital simulation and statistical analysis to compare the performance of the production line before and after the proposed improvements. The validation was carried out using three scenarios: AS-IS (current situation), TO-BE Taguchi (quality optimization scenario), and TO-BE SMED 4.0 (efficiency optimization scenario).

A. Validation Methodology

The methodological development was based on a digital simulation model of the recycled paper tray molding line, developed in SIMIO Software by defining entities, resources, flows, and constraints according to actual plant conditions. Primary entities (trays, molds, and operators) and secondary entities (drying, transport, and quality control equipment) were identified, together with controllable inputs (mold temperature, vacuum time, pressure, and number of operators) and uncontrollable inputs (ambient humidity, failure times, and material variability).

Before simulation, plant data were processed in Arena Input Analyzer, fitting probability distributions to representative statistical functions to ensure model consistency and accurately reproduce system behavior under controlled stochastic conditions.

The model was executed using multiple replications over a full workday simulation horizon. Results were analyzed through descriptive and inferential statistics, comparing quality and efficiency indicators across scenarios.

B. AS-IS Scenario

The AS-IS scenario in Fig. 4, represents the current situation of the molding process before the implementation of the improvement model. This scenario allowed the identification of the main bottlenecks and the magnitude of the waste and defects generated. The AS-IS model showed a defective product rate of 10.28%, 21 unscheduled shutdowns due to incorrect parameters, and a changeover time of 24 hours. These results confirm low process stability and a significant dependence on manual intervention.

The simulation of this scenario served as a baseline for subsequent comparisons, validating that the digital model adequately reproduced the plant conditions.

C. TO-BE Taguchi Scenario

The second scenario, TO-BE Taguchi, integrates the optimal conditions defined by the Taguchi Method with the Poka Yoke 4.0 system. Molding parameters (temperature, pressure, humidity, and vacuum time) were adjusted to their optimal levels, while the digital Poka Yoke system with control sensors enabled automated monitoring of critical variables, reducing operational deviations. As a result, the defective product rate decreased to 2.0%, along with a proportional reduction in unscheduled downtime, confirming the synergistic effect of statistical optimization and digital control on process quality (See Table VI).

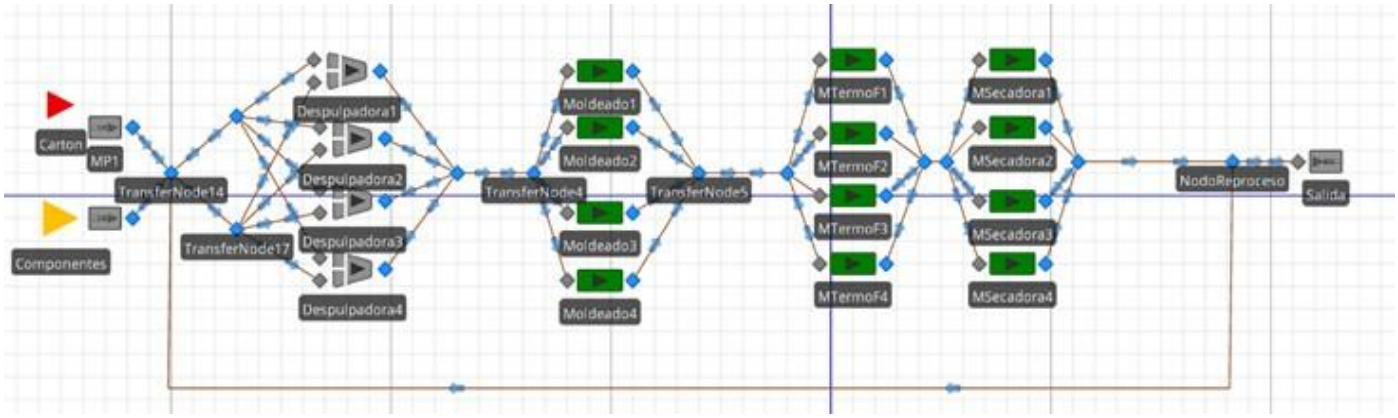


Fig. 4. AS-IS SIMIO System

TABLE VI
RESULTS OF THE TO-BE TAGUCHI SCENARIO

Indicator	Average Value (10 Replics)
Finished Products	28,762.40 Units
Products Without Reprocessing	28,184.50 Units
Products With Reprocessing	577.90 Units
Defect Index	2.00 %
Simulated Total Time	30 Days

TABLE VII
RESULTS OF THE TO-BE SMED 4.0 SCENARIO

Indicator	Average Value (10 replics)
Finished Products	37,292.00 Units
Products Without Reprocessing	33,471.20 Units
Products With Reprocessing	3,820.80 Units
Defect Index	10.25 %
Simulated Total Time	30 Days

The application of the Taguchi Method resulted in an 80.5% reduction in the number of reprocessed products compared to the current state. The process maintains the same overall efficiency, but with greater stability and less dispersion, generating a substantial improvement in quality and resource utilization.

D. TO-BE SMED 4.0 Scenario

The third scenario, TO-BE SMED 4.0, focused on reducing downtime and improving equipment availability. The SMED methodology, adapted to the digital environment, was applied, separating and standardizing mold changeover operations, supported by IoT sensors and data dashboards.

The model allowed for the detection of micro-times not visible in conventional analysis, leading to a restructuring of internal and external activities. As a result, changeover time was reduced from 24 to 14.4 hours, meeting the goal of ≤15 hours established in the performance indicators (See Table VII)

The results show a 29% increase in overall productivity compared to the baseline scenario. Despite maintaining the same defect rate, the total output volume increases, demonstrating that the implementation of SMED 4.0 significantly improves overall efficiency and resource availability.

Overall results of the ape run-in experiments involving the AS-IS scenario and the two scenarios (TO-BE Taguchi and To Be SMED 4.0).

E. Metrics-traffic-lights-results

The results of the three scenarios were compared using key performance indicators (KPIs). The analysis demonstrates that the proposed model achieves a comprehensive improvement: a reduction in the defect rate, a lower frequency of unscheduled downtimes, and a substantial reduction in changeover time.

The comparative results are presents in Table VIII, evaluating the metrics obtained against the established target values.

TABLE VIII
TRAFFIC LIGHT MATRIX OF SIMULATION RESULTS

Indicator	As-Is	To-Be	Target	Result
Defective Product Index	10.28%	2%	≤ 2%	DONE
Number of Unscheduled Stops due to Incorrect Parameters	21 per Month	7 per Month	≤ 7 per Month	DONE
Time of Change Over	24 Hours / Month	14.4 Hours / Month	≤ 15 Hours / Month	DONE

The matrix demonstrates that the simulation model accurately represents the actual production system, validating its reliability as a decision-making tool. In the AS-IS scenario, the simulated results match the actual values reported in the Contribution, confirming the accuracy of the implemented parameters and time distributions.

Based on this validated baseline, the TO-BE scenarios show significant improvements. The Taguchi method reduces the defective product rate from 10.28% to 2%, achieving the quality target through statistical optimization. SMED 4.0 increases overall system efficiency by 30%, reduces changeover time by 40%, and decreases unscheduled stops from 15 to 7 per month, improving operational availability and productive capacity.

Together, both strategies create a positive synergy: Taguchi enhances product quality, while SMED 4.0 improves process speed and stability, achieving or exceeding the target values. Overall, the results confirm the technical relevance of the implemented tools and demonstrate an operational transformation aligned with continuous improvement and Industry 4.0, resulting in a more efficient, reliable, and competitive process.

F. Economic Evaluation

In addition to the technical and operational analysis, an economic assessment evaluated the financial viability of the proposed model. The implementation of the Taguchi methodology and SMED 4.0 reduced for the first-year operating costs by 15.33% (S/ 2'755,760), mainly through lower defect rates, shorter setup times, and fewer unplanned stoppages.

The financial analysis utilizes an Economic Cash Flow (ECF) for 3 years and uses the Cost of Capital (COK) of 17.14% per year, so yielded a positive Net Present Value (NPV) of S/ 3'131,093 and an Internal Rate of Return (IRR) of 153%, well above the COK. These results confirm the model's profitability and sustainability, with a payback period of less than one year (9 months). Thus, integrating Lean tools with Industry 4.0 technologies could be a financially viable strategy for optimizing resources in manufacturing SMEs. Fig. 5 shows the corresponding ECF.

		0	1	2	3
Savings			2,755,760	2,810,875	2,867,093
Incomes			853,240	870,305	887,711
Operating Costs			- 426,620	- 435,152	- 443,855
EBIT			**3,182,380**	**3,246,028**	**3,310,948**
IR	29.5%		- 938,802	- 957,578	- 976,730
Worker Participation	10.0%		- 318,238	- 324,603	- 331,095
Investment - Taguchi Method		- 154,128			
Investment - Digital Twins		- 813,276			
Investment - SMED 4.0		- 222,528			
ECF		**-1,189,932**	**1,925,340**	**1,963,847**	**2,003,124**
EFC @ 17.14%		-1,189,932	1,643,623	1,431,190	1,246,212
Accumulated ECF @17.14%		-1,189,932	453,691	1,884,880	3,131,093

Fig. 5. Economic Cash Flow (ECF)

G. Evaluation of Non-Economic Impacts

Complementarily, an assessment of the non-economic impacts associated with the model was performed, encompassing social, organizational, and environmental dimensions.

From a social perspective, the incorporation of digital monitoring systems and predictive control reduces personnel exposure to repetitive or hazardous tasks, thereby improving occupational health and safety. At the organizational level, training personnel in Lean methodologies and digital tools strengthens technical competencies, promotes active participation in continuous improvement initiatives, and consolidates a sustained culture of innovation.

Regarding environmental impact, the reduction in defect rates and idle time results in lower consumption of energy, water, and raw materials, contributing to energy efficiency and the environmental sustainability of operations. These improvements align with the principles of green manufacturing and reinforce corporate social responsibility within the industrial sector.

Overall, the findings confirm that the proposed model could generates economic, social, and environmental value, coulding positioning it as a comprehensive solution for continuous improvement and a sustainable transition toward Industry 4.0.

V. DISCUSSION

The validation results confirm that integrating Lean Manufacturing tools with Industry 4.0 technologies significantly improves quality and operational efficiency in low-digitalization manufacturing environments. The proposed framework, which combines the Taguchi method, Poka Yoke 4.0, SMED 4.0, and a Digital Twin, demonstrated its potential to improve process quality and production efficiency under the evaluated conditions both process quality and production efficiency.

The Taguchi-based TO-BE scenario reduced the defect rate from 10.28% to 2.0%, validating the effectiveness of statistical optimization for stabilizing critical process parameters. This improvement is consistent with previous studies reporting defect reductions between 40% and 70% through Taguchi-based optimization [26], [27]. The integration of Poka Yoke 4.0 further enhanced process reliability by enabling continuous digital monitoring and early deviation detection, consistent with

intelligent quality control approaches reported in [28] and [29].

The distinction between the two technologies is relevant to the interpretation of the proposed framework. In the present study, the Digital Twin constitutes the data-driven virtual environment that represents and analyzes the physical process, whereas Poka Yoke 4.0 represents the error-prevention logic operating on the information generated by this environment. Thus, the contribution is not the use of the Digital Twin as a Poka Yoke itself, but the integration of Digital Twin capabilities with digital Poka Yoke mechanisms to establish a closed-loop quality-control approach. The Taguchi method defines statistically optimized operating conditions, the Digital Twin continuously evaluates process behavior against these conditions, and the Poka Yoke 4.0 layer detects deviations and triggers preventive or corrective responses.

Likewise, the SMED 4.0 implementation reduced changeover time from 24 to 14.4 hours, achieving a 40% reduction comparable to previous digital SMED applications [10], [11]. Unlike most reported studies, however, the proposed model suggests that similar improvements may be achievable using affordable digital technologies and existing infrastructure, extending the applicability of SMED 4.0 beyond highly automated production systems.

The sequential integration of the proposed components revealed a potential operational synergy within the evaluated scenarios. Process stabilization through Taguchi and Poka Yoke 4.0 created the conditions for the successful implementation of SMED 4.0, supporting the Lean digitalization principle that standardized processes are essential for effective digital transformation [4], [12]. Moreover, the Digital Twin enabled virtual validation of process improvements before implementation, reducing operational risk while supporting evidence-based decision-making [20], [30].

The proposed framework also contributes to sustainable digital transformation by promoting gradual technological adoption rather than intensive automation. This progressive approach is particularly suitable for Latin American SMEs, where financial and technological constraints often limit Industry 4.0 implementation [7], [32]. The integration of statistical optimization, digital monitoring, and simulation provides a practical roadmap toward digital manufacturing while potentially reducing the technological and financial barriers associated with implementation.

From a scientific perspective, this research demonstrates the value of combining experimental design with cyber-physical simulation. The Digital Twin served not only as a validation platform but also as a predictive decision-support system for evaluating alternative operating scenarios prior to potential physical implementation. By integrating statistically validated experimental data into the virtual environment, the proposed framework establishes a continuous feedback loop that improves prediction accuracy and supports reproducible engineering research [20], [30].

The incorporation of Poka Yoke 4.0 further strengthens process reliability by transforming conventional quality inspection into proactive digital error prevention through real-time monitoring and automated alerts. This capability aligns with emerging concepts of predictive and cognitive manufacturing systems described in [26] and [31].

Operationally, the proposed model increased productivity while reducing defects, downtime, rework, and maintenance requirements, reinforcing previous findings on the economic benefits of integrating Lean Manufacturing with digital technologies [12], [33]. Likewise, lower defect generation and shorter production interruptions contribute to reduced material waste and energy consumption, supporting sustainable manufacturing objectives [33].

Although validation was performed in a Digital Twin environment, the consistency of the simulated results with previous research supports the model's feasibility. Future studies should validate the framework under industrial operating conditions.

Overall, this study develops a framework with potential for scalability and reproducible hybrid improvement framework that integrates Lean Manufacturing and Industry 4.0 technologies. Beyond its practical contribution to manufacturing SMEs, the model offers an accessible methodology for digital transformation and a valuable reference for future research on smart manufacturing, continuous improvement, and sustainable industrial engineering.

VI. Conclusions

The integrated model achieved the overall objective of improving both quality and efficiency in the recycled paper tray production line. Digital simulation reduced the defect rate from 10.28% to 2.0%, representing an 80.5% improvement and confirming the effectiveness of combining statistical optimization with digital control in low-digitalization manufacturing environments.

For the first objective, integrating the Taguchi method, Poka-Yoke 4.0, and the Digital Twin stabilized critical molding parameters and reduced unscheduled downtime caused by incorrect settings from 21 to 7 events per production cycle. Regarding the second objective, SMED 4.0 reduced changeover time from 24 to 14.4 hours (40%), surpassing the target of ≤15 hours by standardizing activities and using digital tools to analyze setup operations.

The third objective was achieved through real-time monitoring and predictive maintenance within the Digital Twin, enabling early fault detection and reducing unplanned downtime. Likewise, the TO-BE simulation supported the fourth objective by improving material flow, synchronizing operations, and enhancing production planning and decision-making.

Overall, the results demonstrate that integrating Lean Manufacturing with Industry 4.0 technologies creates a scalable and sustainable improvement model that enhances productivity, reduces waste, and increases process stability, making it suitable

for manufacturing SMEs and future research on continuous improvement and digital transformation.

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