

Original Article

Resource-Sensitive Lean-TPM and SMED Intervention to Elevate OEE: A Case Study of a Peruvian Bottle Manufacturer

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Abstract - The study expanded on earlier uses of Lean and TPM in manufacturing and addressed long-standing inefficiencies in plastic bottle SMEs. It focused on pressing problems like long mold changes, frequent unscheduled downtime, and calibration delays that limited capacity and quality. Through coordinated trials, checklists, operator training, and low-cost interventions, an integrated Lean-TPM model with SMED was put into practice. The pilot reduced estimated annual losses by PEN 76,109.98 (17% of the 500 ml line profit) by increasing OEE from 70.76% to 81%, availability from 86.76% to 91%, performance from 86% to 93%, and quality from 94.49% to 96%. Mold change time decreased from 96 to 55 minutes (-43%) and calibration from 52 to 44 minutes (-15%). These results illustrated that targeted, resource-conscious actions yielded quantifiable operational and financial benefits, contributing to academic discussions on Lean-TPM integration and realistic adoption strategies for limited SMEs. Multisite replication, extended monitoring, and low-cost condition monitoring and adoption were all suggested by the study.

Keywords - Lean Manufacturing, Total Productive Maintenance (TPM), SMED (Quick Changeover), Overall Equipment Effectiveness (OEE), SME Production Efficiency.

1. Introduction

The plastic packaging industry, especially SME producers of plastic bottles, is a critical sector for industrial development worldwide. In many countries, it provides essential consumer goods and employment while facing rising demand for packaging materials. For example, the plastics manufacturing sector in Peru has grown markedly and now contributes about 4% of the nation's industrial GDP, employing over 200,000 workers [1]. These firms are overwhelmingly micro- and small enterprises (over 90% of plastics firms in Peru are SMEs) [2], like patterns throughout Latin America. In fact, small and medium enterprises account for roughly 99% of formal businesses and about 75% of employment in Peru's economy [3]. This means that plastic bottle manufacturers – often organized as SMEs – play a major economic and social role in the region. The global plastics market also continues to expand (for diverse uses from packaging to construction materials), underscoring the strategic importance of bottle producers internationally [4], [5].

Given this prominence, the smooth operation of plastic bottle plants is vital. However, many studies note that these SMEs often operate with low equipment availability and poor

Overall Equipment Effectiveness (OEE). For instance, analysis of a Peruvian plastics company found that average machine availability was only about 70.8% due to frequent unplanned downtime [6]. Such underutilization is attributed to constant machine breakdowns, lengthy setups and calibrations, and long idle periods. Machines in these plants often stopped for repairs or adjustments, inflating maintenance hours and reducing output. Several case studies highlighted these issues: surveys of small manufacturing lines showed that lacking preventive maintenance led to high breakdown rates, and SMED studies reported excessively long mold-change times for plastic injection machines when setups were not streamlined. For example, one industrial case noted that poor maintenance and tool-change procedures kept OEE below world-class levels (around 50–60% OEE compared to an 85% benchmark). Similarly, studies of apparel and textile SMEs (an analogous labour-intensive sector) emphasized that process wastes (excess movement, long changeovers, quality rework) dramatically increased unproductive time and defect rates [7], [8]. In plastics SMEs specifically, the lack of spare parts and inefficient operator routines further contributed to long machine downtime and scrapped product. In summary, small plastic-bottle factories routinely suffered from low OEE because equipment availability was impaired by breakdowns,



changeovers took excessive minutes or even hours, and idle waiting times accumulated.

So, fixing these production problems was very important for quality, competitiveness, and long-term success. Targeted process improvement could greatly boost output capacity and product quality by cutting down on downtime and non-productive time. Lean Manufacturing and Total Productive Maintenance (TPM) are two well-known ways to deal with these problems. To make things run more smoothly and efficiently, they focus on getting rid of waste (according to Lean) and stopping breakdowns (according to TPM). For instance, using Lean tools like SMED (Single-Minute Exchange of Dies) in a planned way can greatly reduce the time it takes to switch over, and TPM practices (especially Autonomous and Planned Maintenance) make sure that machines are always in good working order. A study of a plastics plant found that combining SMED and Total Preventive Maintenance (TPM) increased overall OEE from 61.9% to 80.9% by cutting down on both downtime and rework [9]. Textile and garment SME case studies also showed that even basic 5S and standard-work programs could cut defect rates by more than 60% and boost equipment effectiveness by about 35% [10]. Reviews of the plastics and general manufacturing literature show that Lean initiatives greatly improve operational performance: they consistently cut down on waste, speed up lead times, improve product quality, and increase machine use [4], [7]. These changes led to more work getting done, better on-time delivery, and more resilience for small and medium-sized businesses that were under competitive pressure. In short, Lean and TPM were shown to work in manufacturing settings to make things more efficient and cut down on defects [4], [7].

Despite its promise, however, there was a notable gap in the literature concerning Lean/TPM specifically for plastic bottle manufacturers in SMEs. Most published work on Lean-TPM models has been conducted in larger companies or in different industries (e.g., automotive, textiles, electronics). Few studies had targeted small plastics producers or bottle- and container-making lines, and even fewer had examined Latin American SMEs in this sector. For instance, a recent analysis explicitly noted that “there is little research in the plastics industry” on combined Lean and TPM strategies, particularly for Latin American SMEs [1]. Prior work tended to focus either on broad theoretical frameworks or on unrelated sectors; the case of plastic container blowing lines – which involve injection and blow-moulding processes – remained underexplored. In other words, the literature lacked structured models that integrated SMED and TPM to optimize bottle production in small-scale plants.

To fill this gap, the present research developed a production model based on Lean Manufacturing tools (notably SMED for quick mold changes) and TPM practices (preventive and autonomous maintenance pillars). The

proposed model was tailored to the high-mix, low-volume context of plastic bottle SMEs, addressing the specific causes of downtime (frequent machine stops, lengthy calibrations) identified above. In doing so, it went beyond existing studies: for example, in garment SMEs, a Lean-TPM model achieved a 60.5% defect reduction and 36.6% OEE increase [10], and in metalworking SMEs, Lean-TPM raised OEE from ~65% to 81% [1]. The contribution adapted these concepts to bottle production. By comparing to these cases, the novelty became clear: the model targeted plastic resin injection/blow molds and considered the idiosyncrasies of bottle output (such as calibration for different sizes). Preliminary simulation and pilot results indicated that implementing SMED and TPM in concert could push OEE well above 80% in such plants, similar to or exceeding gains seen elsewhere. Thus, this work aimed to bridge the Lean-TPM literature gap for Latin American plastic-bottle SMEs and to quantify the expected productivity and quality gains relative to prior models.

In summary, the high economic importance of plastic bottle makers (especially SMEs), combined with their chronic production inefficiencies, motivated this study. The existing research showed that Lean/TPM approaches yielded large benefits in comparable settings [4], [9], but that specific attention to plastic packaging SMEs was lacking. This paper, therefore, proposed and validated an integrated Lean-TPM production model and demonstrated how it improved upon prior results by addressing the unique waste sources in bottle blowing and contributing novel operational insights to the field.

2. Literature Review

2.1. Lean Manufacturing in Plastic SMEs

The literature found that Lean Manufacturing was fundamental to eliminating waste and improving efficiency in plastic production plants. Recent studies highlighted that Lean sought to minimize defects, overproduction, and waiting times through practices such as 5S, Kanban, and SMED [5]. For example, Poves-Calderón et al. applied Lean techniques (TPM and SMED) in a Peruvian plastic SME, achieving a 20% increase in productivity [11]. Similarly, Cordova et al. found that the implementation of Lean Manufacturing increased machine availability and accelerated processes in a small plastics firm, removing bottlenecks in mold changeovers [12]. Taken together, these experiences validated that Lean Manufacturing optimized the efficiency and competitiveness of plastic SMEs through process standardization and elimination of non-value-adding activities [13], [12].

2.2. Reduced Times: SMED Methodology

The SMED (Single-Minute Exchange of Die) method was applied to reduce tooling changeover times by converting internal activities (performed with the machine stopped) into external ones. In the plastics industry, case studies produced striking results with SMED. For instance, Marcella and Widjajati used SMED on an injection-molding machine and

decreased mold change time by approximately 16.7% [13]. Likewise, Agung and Hasbullah reported an 18% reduction in setup times after applying SMED in another injection-molding plant [14]. These shortened setup times resulted in greater production flexibility and faster response to demand; they also reduced line downtime [15], [13]. In summary, SMED implementation in plastic micro- and small enterprises accelerated product changeovers, increased machine availability, and directly streamlined production flow [4], [6].

2.3. Total Productive Maintenance (TPM)

TPM functioned as a comprehensive maintenance philosophy aimed at maximizing equipment efficiency. In the plastics sector, TPM implementation raised OEE (Overall Equipment Effectiveness) and reduced unplanned stoppages. Moreno et al. deployed TPM strategies (scheduled maintenance and operator activities) in a Peruvian container plant and increased OEE from 61.9% to 80.9% [16] by lowering failures and rework. Likewise, Cordova et al. developed a Lean-TPM model in which preventive practices improved equipment availability and optimized production flow in a plastic SME [12]. Overall, reports indicated that adopting TPM—with pillars such as autonomous and planned maintenance—increased equipment reliability and prevented major failures, yielding measurable gains in productivity and quality [12], [16].

2.4. Autonomous Maintenance: Empowering Operators

Autonomous maintenance (the first TPM pillar) involved operators in the daily care of equipment. Operators thus learned to clean, lubricate, and adjust their machines, detecting early deviations. Case studies corroborated the benefits: when autonomous maintenance was applied on a molding line, operator sensitivity to equipment condition increased and unexpected stoppages decreased [16]. In addition, Cordova et al. observed that adding routine maintenance activities (such as daily inspections) raised machine availability in a small plastics plant [3]. In short, training and empowering workers to perform basic checks and simple adjustments improved process stability and reduced reliance on external technicians [12], [16].

2.5. Planned Maintenance: Preventing Stoppages

Planned maintenance (the third TPM pillar) was based on scheduling preventive or predictive interventions according to equipment life cycles. This strategy extended machine life and reduced critical failures. It was reported that, in plastic SMEs, planning activities—such as regular cleaning, sensor calibration, and vibration analysis—increased availability and prevented major stoppages [16], [12]. Calderón-Gonzales et al. noted that predictive maintenance based on monitoring (vibration, thermography, etc.) anticipated failures before they interrupted production, helping to keep production schedules stable [11], [16]. In conclusion, planned maintenance proved essential for plastic-container SMEs to achieve more predictable processes with reduced downtime and costs,

thereby ensuring a continuous and efficient production flow [11], [16].

3. Contribution

3.1. Proposed Model

Figure 1 illustrates the integrated production model developed for a small-scale enterprise dedicated to the manufacture of plastic bottles in the two predominant volumes of 500 ml and 1 litre. Anchored in Lean principles and Total Productive Maintenance (TPM), the architecture was designed to systematically minimize operational losses and to bolster machine availability. The model is realised through an interlacing of two core modules: TPM, focused on empowering operators to carry out both autonomous and strategically scheduled maintenance, thus sustaining machine reliability and curtailing unforeseen downtime; and Single Minute Exchange of Die (SMED), concentrated on effecting significant and sustained reductions in the durations required for Mold changeovers and related set-up tasks, thereby enhancing production line adaptability. The framework is organised in a linear progression: an initial evaluation stage identifies roots of sub-optimal availability and waste; next, maintenance efforts and quick-change actions are implemented in synchrony; and the cycle concludes with attained improvements being translated into smoother process flows and maximised utilisation of the existing production capacity. Collectively, the model is articulated as an actionable and transferable blueprint for manufacturing Small and Medium-Sized Enterprises (SMEs) pursuing heightened competitive positioning through deliberate process refinement.

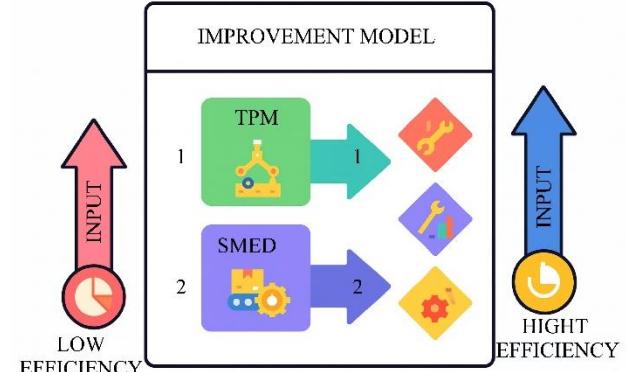


Fig. 1 Proposed Model

3.2. Model Components

The present model advances a pragmatic response tailored to small and medium-sized manufacturing enterprises seeking systematic improvements in production performance but confronted continuously by limited resources and broad product-mix variability. It synthesises core lean principles and established equipment-centred reliability methodologies to deliver an integrated roadmap that a) minimises operational losses and b) speeds responsiveness across high-mix production scenarios. The theoretical novelty resides, first, in

the delineation of the interactive levers that bind maintenance-led reliability to swift-change capability, and, second, in the empirically anchored exposition of this alignment within the specific context of plastic bottle manufacturing, where operational scope is limited to two predominant nominal sizes of 500 and 1,000 millilitres.

3.2.1. Conceptual Framework and Rationale

This framework articulates an integrative model that positions process reliability and changeover agility as mutually reinforcing dimensions of operational excellence. Reliability is operationalized as the sustained ability to deliver target output rates over long horizons without unscheduled stoppages; agility is the analogous capacity to pivot between differing product specifications with minimal delay and operational turbulence. By bringing both constructs into a single frame of reference, the model speaks directly to the operational profiles of many small-scale packaging operations, characterized by high-frequency format change, low or moderate output levels, aging physical assets, and constrained maintenance staffing. The theoretical justification for their simultaneous study is that enhanced asset reliability dampens the variability that typically burdens short-notice format changes, while tighter changeover cycles directly expand the available production window. Consequently, the framework prioritizes interventions that yield simultaneous improvements—initiatives that lower machine downtime while compressing changeover duration—over piecemeal strategies directed at one or the other metric. The resulting design logic influences the sequencing of operational activities, the prioritization of capital and human resource allocation, and the structure of performance indicators, all configured to favour outcomes that advance both reliability and agility rather than rigid single dimensions.

3.2.2. TPM Component - Structure, Phases, and Practical Steps

The TPM component organizes interventions around incrementally building workforce capability and systematically removing losses linked to equipment. The initial phase consists of a diagnostic assessment, during which the team charts machine histories, catalogues standard failure modes, and records the contextual conditions surrounding each stoppage. This assessment employs straightforward, yet thorough, methods to capture patterns, using visual inspections, basic failure trees, and time-logged records of interruptions. The subsequent phase focuses on autonomous maintenance, in which operators take on responsibility for daily cleaning, periodic lubrication, and simple adjustments. The methodology prescribes limited, unambiguous tasks that operators complete every day, supported by checklists and visual prompts that guarantee repetition and accuracy. The third phase introduces a planned maintenance schedule that aligns preventive tasks with production cycles and honours the sequencing restrictions of the two bottle formats; planned interventions seek to eliminate root causes identified during

the diagnostic phase and to cut the frequency of minor stoppages that escalate into major failures. Simultaneously, training and skills development advance alongside these phases, enabling multidisciplinary teams to receive targeted instruction in fault identification and basic corrective interventions.

3.2.3. TPM Component — Structure, Phases, and Practical Steps

The Total Productive Maintenance (TPM) module advances the rationalization of spare-part catalogues alongside the uniform codification of operating protocols, thereby lowering the mean time to repair and expediting restoration following production disturbances. Iterative, micro-scale improvement cycles—managed through abbreviated Kaizen events—systematically reinforce performance gains, locking refined practices into the operational cadence of the workforce and consolidating advances into habitual executor competencies.

3.2.4. SMED Component — Structure, Phases, and Practical Steps

The SMED framework explicitly targets the reduction of idle time when transitioning between the 500 ml and 1-liter container lines, while also assuring that the resulting procedure becomes stable and replicable. Implementation commences with a detailed changeover process map, which breaks the entire sequence into atomic steps and highlights those actions that can occur without halting the machine. The analysis subsequently directs attention toward externalizing preparatory work—gathering tools, Molds, and raw materials in advance of any machine engagement—and converting internal actions to the exterior domain whenever practical. The approach advocates the adoption of low-footprint fixtures, indexed fasteners, and pre-packaged jigs to expedite mechanical adjustments, while also mandating mobile setup stations and shadow-branding of tools to guarantee ergonomic and immediate access. Continuing to internal tasks, the methodology seeks to curtail unproductive motion, refine cooperation between team stations, and re-engineer touch points that have traditionally mandated fine adjustments. Central to the SMED process is a structured regimen of iterative trials, whereby every proposed modification is subjected to a series of timed repetitions and photographic auditing, yielding a documented record of incremental refinements. The outcome is the formal integration of the optimized procedure into the operational framework through revised standard work instructions, targeted coaching for team members, and cross-verified checklists that formalize the sequence of events confirmed during the validation runs.

A deliberately designed pathway alleviates cognitive workload for operators throughout the changeover process and provides a normative standard, enabling subsequent, incremental improvement

3.2.5. Integration Mechanisms: Coordinating TPM and SMED

Successful integration depends on coordination mechanisms that bring Total Productive Maintenance (TPM) and Single-Minute Exchange of Die (SMED) together to work toward a common goal for the company, rather than separate, unsatisfactory benefits. The routine begins with collaborative diagnostic rounds, during which production and maintenance personnel examine the same causes of downtime and persistent changeover delays in a single session. The shared review helps people get to know each other, talk about words, and share ownership. Because of this, the maintenance funnel is limited. Preventive work can only be done during certain times that are connected to SMED trials that are going on at the same time, so formal changeover validation does not have to stop. Minor tasks are broken up into regular work periods, which makes it easy to set up experiments. Also, simple log forms are used to store availability events and changeover clock data. These forms are then moved to a regular review cycle. Cross-functional groups that include engineering, manufacturing, and maintenance look at embedded diagrams, find indicators of friction that happen over and over again, and rank the paths of countermeasures. Executive scaffolding makes daily work more official. An agile project board sorts "fast win" conversions, gives out small upgrade budgets (like for small tooling jigs), and approves experimental changes. Integration also uses levels of stacked problem-solving. Wear and tear cause changeover strain, but TPM-defined processes lead to exact corrective maintenance. But problems that come up during set-up sequences because of unnecessary maintenance force SMED teams to change how they do things, which makes things less tense.

The two dimensions work together to make a strong feedback loop, where changes in one area lead to changes in the other area in a systematic way.

You need to choose a specific way to use the strategy in a small business that makes both 500 ml and 1-liter bottles because there is not much floor space, employees do not have the right skills, and you cannot invest in everything. The first thing to do is look over the layout and process for both lines. This shows that their handling points, material trajectories, and mold couplings are all the same, which means that standardizing tooling gains across all formats is a good idea. The next step is to look for small investments that will pay off big. These are quick-change clamps made from stock bar, modular mold adapters made during downtime, and roll-along setup racks made from thin aluminium extrusions. These kinds of actions keep investments liquid and stop the costs of big die bases. In a polyvalent model, workers learn how to do both routine setup for Cycle Time Level and predictable maintenance. People now have more general knowledge that helps them act appropriately during shift changes and keeps idle time to a minimum, instead of relying on one expert. There are two to three strategically dense changeovers on the

master schedule, and the lot sizes are short and set ahead of time. The master timetable shows that these lot sizes are next to each other. This rhythm uses the benefits of a fixed size that can be repeated while keeping the important route stable for future runs with much demand. Quality gating and material reconciliation have also been moved to before the operating session. Digital micrometers and periodic callipers measure aligned gauges outside of the working takt, which makes the changeover lifetimes shorter overall. The model also makes it easier to keep up with visual controls and standard work scripts. For instance, brightly coloured operators' checklists and colour codes on the dash help temporary and part-time workers meet and exceed the normal average and show the point at which shift tendency becomes zero drift.

The contextual calibration mitigates supply constraints by prescribing the least quantity of critical spares and pinpointing the lead times required for procurement. This information enables maintenance schedules to stay realistic and manageable within the acquisition cycles characteristic of the subject-matter expert.

3.2.6. Monitoring, Continuous Improvement, and Knowledge Retention

The model prescribes a feasible monitoring framework that aligns the need for data with the constrained management capacity typical of small enterprises. Monitoring centres on a small set of straightforward metrics collected via operator-friendly observation sheets or uncomplicated digital logs, prioritising the tracking of changeover times, the incidence of short unscheduled stops, and compliance with daily autonomous maintenance checklists. These metrics are aggregated and reviewed monthly within improvement cycles that reveal trends and experimentally interrogate presumed root causes.

Simultaneously, the pillar of knowledge retention is strengthened. The model advocates the production of compact illustrated setup guides and brief video demonstrations that render implicit practices explicit. Such records are accessible and readily reviewed, lowering the cognitive load needed to recall optimal methods. Paired with these artifacts, cross-training sessions spread critical competencies across multiple individuals, thus safeguarding improvements against the attrition that can occur during personnel absences. Continuous improvement itself is executed through the methodical trial of small, isolated experiments rather than through expansive initiatives; the firm introduces one modification, monitors its impact over a predetermined observation window, and elects to institutionalise, modify, or retract the change. This incremental, disciplined experimentation cultivates a resilient learning culture, attuned to the firm's operational pace and resource constraints. The integrated monitoring and knowledge systems consequently converge to preserving and embedding performance gains, ensuring that enhancements

are firmly woven into the everyday operational practices of the firm.

3.2.7. Critical Analysis: Constraints, Scalability, and Organizational Factors

The framework sets out a number of limits that define the highest expectations and the limits that small-scale manufacturers can work within. The most important of these is the lack of resources, both money and people, which creates a hierarchy that affects the choice of tooling improvements and limits the scope of planned maintenance plans. The framework thus emphasizes interventions that demonstrate significant cost-effectiveness ratios, while concurrently indicating that specific high-reliability behaviors are contingent upon achieving a critical operational mass. The sociocultural structure of the enterprise represents an additional modality; persistent vertical authority patterns and a reluctance to redefine functional jurisdictions may obstruct the transfer of maintenance jurisdiction to the machine operative level. To reduce this kind of resistance, the framework includes shortened, results-oriented proofs of concept that show clear benefits and, by being visible, get stakeholder support. Scalability imperatives necessitate a modular framework—each intervention is designed to utilize a limited set of distinct actions that produce measurable outcomes, thereby facilitating gradual enhancement. Finally, extrinsic linkages, like supplier replenishment cycles for consumables or the restriction of proprietary tooling, require preparatory contingencies. To reduce the risk that comes from transactional asymmetric dependencies, the framework suggests practical steps, such as focusing on nearby sources or setting a limited reserve net.

3.2.8. Concluding Remarks and Practical Value

The proposed model gives a practical framework that links maintenance reliability with the ability to change quickly through a sequential, low-cost program made for small plastic bottle makers. Each phase is kept open, relying on small, low-cost changes that are important for the business and help it make small gains without having to make significant investments. Additionally, making sure that knowledge is documented on a regular basis helps to stop people from leaving the organization, which helps to keep improvements in the organization's memory. The model strengthens the company's ability to provide stable operations while also allowing for the flexibility needed for different types of cosmetic and functional bottles by combining equipment maintenance, setup-systems design, and skill development into a single operational discourse. By providing operations that last even when resources are limited, the framework strengthens the competitive position in a field where design changes happen quickly.

3.3. Model Indicators

The “Model Indicators” subsection articulates the methodological apparatus instantiated to track the Lean–TPM

production schema at the subject micro-scale plastics bottler. The exposition prioritizes a lightweight, executive approachable topology that seizes machine dynamics, transition workflows, and intra-station constancy without overburdening the management apparatus. The regime has loops of quotidian fact-gathering and succinct performance audits incorporated into the cadence of standard workflows, thereby normalizing the translation of empirical observation into calibrated corrective action. The effect is the translation of tacit operational data into targeted interventions, fostering a gradual and cumulative reinforcement of production discipline throughout the enterprise. The subsequent paragraph elaborates on the indicators utilized to evaluate the proposed model.

OEE — Overall Equipment Effectiveness

OEE measured the joint effect of availability, performance, and quality on productive time, expressing the proportion of scheduled time that produced conforming parts at the ideal speed. It summarized equipment efficiency as a single composite measure.

$$OEE = Availability \times Performance \times Quality$$

Availability Rate

Availability Rate quantified the fraction of planned production time during which equipment was running and capable of producing, after excluding stoppages; it reflected true machine uptime for productive operations.

$$Availability = \frac{\text{Operating Time}}{\text{Planned Production Time}}$$

Quality Rate

Quality Rate represented the share of finished units that met specifications (good units), excluding rejects and rework, thereby indicating the effectiveness of process quality controls.

$$Quality = \frac{\text{Good Units}}{\text{Total Produced}}$$

Performance Rate

Performance Rate compared actual throughput against the theoretical ideal, accounting for reduced speed and minor stops; it measured how closely production ran to nominal cycle time.

$$Performance = \frac{\text{Ideal Cycle Time} \times \text{Total Produced}}{\text{Operating Time}}$$

Setup Time (Mold Change)

Setup Time (Mold change) recorded the elapsed minutes required to replace molds and complete mechanical adjustments; the indicator was expressed as the average time per mold change.

$$\bar{T}_{\text{mold}} = \frac{\sum_{i=1}^n T_{\text{mold},i}}{n}$$

Setup Time (Temperature Calibration)

Setup Time (Temperature calibration) measured the minutes spent stabilizing and calibrating process temperature during set-ups; it was reported as the mean calibration duration per event.

$$\bar{T}_{\text{temp}} = \frac{\sum_{i=1}^n T_{\text{temp},i}}{n}$$

4. Validation

4.1. Validation Scenario

The empirical validation of the proposed framework was executed within a multiple-case study properly designed around a Small to Medium Enterprise (SME) devoted to producing plastic containers, with operational headquarters in Lima, Peru. The company was classified as an expanding enterprise, possessing an integrated production facility complemented by storage capabilities, and was characterized by a workforce of limited size and equipment governed by material constraints. Such operational realities invariably influenced both its manufacturing and logistic architectures.

A preliminary diagnostics exercise within the blowing production zone uncovered a critical deficiency in productivity, typified by recurrent equipment downtime and a cumulative erosion of available time, phenomena that had a debilitating effect upon production flow and adverse repercussions upon profit margins. By situating the enquiry within this industrial milieu, the resulting study depicted a credible and archetypal prototype of the national plastics fabrication segment, thereby enhancing the analytical traction of the chronicled causative factors and augmenting the anticipated value of forthcoming remedial actions.

4.2. Initial Diagnosis

The diagnostic phase of the case study revealed an average operational efficiency of 70.76%, substantially below the 85% benchmark typical for comparable processes, directing subsequent analytical attention to principal avenues of efficiency erosion. The principal contributor, machine downtime, constituted 84.66% of the efficiency deficit, with the principal causal categories as follows: mechanical and electrical failures, 45.37%; extended mold changeovers, 16.15%; delays in thermal calibration, 12.76%; and lapses in lubrication scheduling, 10.39%. Non-production time attributable to machine operators represented an additional 8.85% of lost capacity, most arising from training sessions missed per the planned operational calendar. The inadequacy of raw material supplies—impacted by supplier non-conformance—accounted for 6.48% of the efficiency shortfall. Collectively, the observed sources of operational loss manifested an aggregate economic repercussion, conservatively quantified at PEN 76,110, and equivalent to

17% of the annual profit derived from the 500-millilitre line, thereby impeding sustained production flow and weakening the competitive standing of the enterprise within the relevant market.

4.3. Validation Design

A pilot execution of the Lean-TPM operations model was mounted to validate the framework in the highlighted Small-to-Medium-sized Enterprise (SME), spanning a four-month interval and meshing within the habitual production rhythm. The field programme blended selective maintenance schedules, controlled tool-change experiments, and structured operator instruction, with participants completing brief logging formats to permit rapid empirical observation. Outcome appraisal drew upon pre- and post-contrast and incremental procedure reassessment, thus securing pragmatic viability alongside continuing managerial stewardship. Interventions were intentionally low-investment and easily replicable, enabling a solid, evidence-centered appraisal of operational effectiveness and economic soundness within the production environment.

The proposed model was implemented in the case study through a structured intervention plan that was deployed during the validation period. The rollout integrated awareness activities, training, maintenance planning, and setup experimentation, with the participation of management, maintenance staff, and operators. Planned and autonomous maintenance protocols were executed, changeover and calibration times were recorded, and monitoring routines were established. Execution considered predefined resources, Schedule, and budget, and prioritized low-cost, high-impact actions aimed at consolidating sustainable practices within the industrial plastic container production plant.

Overview of the Design and its Methodological Justification

The detailed design presented a dual structure centered on the combination of two complementary techniques: a Total Productive Maintenance (TPM) component oriented to reliability and an SMED component oriented to the reduction of changeover and calibration times. This composition was justified by diagnostic data that showed an initial average efficiency of 70.76% versus a technical benchmark of 85%, in addition to accumulated downtime losses of 38,397 minutes per year on the blow molding machine; these values motivated the need to address both failures and maintenance and agility in equipment configuration.

The methodological approach articulated sequential phases — preparation, pre-implementation, implementation, and consolidation — for each tool, with quantifiable milestones that allowed measurement of advances in availability, performance, and quality. This structure facilitated the prioritization of interventions oriented to rapidly measurable results and low initial capital outlay.

TPM as a Pillar of Reliability and Stoppage Reduction

The section devoted to TPM described the aim of reducing mechanical and electrical failures, which accounted for 17,420 minutes of downtime (45.37% of total losses), through the implementation of two pillars: planned maintenance and autonomous maintenance. In the preparation phase, senior management awareness was promoted and the responsible team was established; in the pre-implementation stage, policies and objectives aligned with the company strategy were defined; during implementation, an annual maintenance program was developed with periodicities defined in operating hours, verification checklists, and a critical spare parts policy. It was made explicit that, by applying these actions, the intention was to recover a substantial proportion of the 32,509 total minutes of stoppage observed in the blow molding line, which supported the hypothesis of improved availability and the consequent contribution to OEE.

Operational Details of Planned Maintenance

The document described concrete procedures for implementing planned maintenance: inventory and classification of failures, preparation of an annual plan that defined intervals in operating hours for preventive interventions, clear roles and responsibilities for supervision and execution, and a system of maintenance checklists to ensure traceability. The potential impact was quantified when the reduction of unplanned repairs — with unplanned maintenance costs estimated at PEN 22,074.83 — was linked to the expected decrease in stoppages, which allowed projection of availability improvements close to the established objective. The strategy included spare parts rationalization, identification of critical items, and agreements with suppliers to reduce lead times.

Implementation of Autonomous Maintenance and Capacity Development

For autonomous maintenance, the training of operators in cleaning, inspection, and lubrication tasks was detailed, as well as the standardization of checklists and internal audits to verify compliance. It was reported that lapses in lubrication had caused 3,989 minutes of downtime (10.39% of total losses), which justified specific training and control actions; furthermore, it was documented that three of six operators did not reach the 80% performance threshold due to absences from training, generating 3,398 minutes of downtime (8.85%). The intervention combined technical training with compliance audits and performance targets to reduce the recurrence of stoppages associated with human intervention.

SMED as a Pathway to Reduce Setup and Calibration Times

The SMED section indicated that the main objective was to decrease mold changeover and temperature calibration times, which, in aggregate, represented 11,100 excess minutes relative to standards (6,200 minutes for mold changes and 4,900 minutes for calibration). The procedure was articulated

in four steps: team organization and time study, separation of internal and external activities, conversion of internal into external activities, and optimization with standardization. Initially, 32 internal activities were recorded for mold change and 9 internal activities for calibration; after conversion, these internal activities were reduced to 30 and 7, respectively, and auxiliary activities were externalized to reduce the adequate machine stoppage time. These measures led to an observed reduction in mold change time from 96 to 55 minutes and in calibration time from 52 to 44 minutes, which directly explained part of the improvement recorded in availability and OEE.

Organization, Recording, and Analysis of Setup Times

During the organization phase, recordings, detailed timekeeping, and photographic documentation of each activity were instituted, which allowed a clear distinction between internal and external operations. The analysis work prioritized converting activities that did not require stoppage into preparatory operations performed in parallel; standardized tool carts, pre-assembly of parts, and mold pre-verification procedures were introduced. Adoption of these practices was supported by empirical evidence obtained from measured times and by the intent to reduce setup variability. The test and adjustment methodology included empirical trials with before-and-after time measurements to validate the effectiveness of each change.

Final Optimization and Standardization of Changeover Work

The optimization stage formalized validated configurations by drafting standardized work procedures, checklists, and recording formats. Mechanisms that were easy to handle (fixtures, quick-release fasteners) were introduced, and small teams were trained to execute setups precisely. Records showed an average reduction of 41 minutes in changeover time and 8 minutes in calibration, which were incorporated into the equipment performance baseline and used to project improvements in line availability. These reductions contributed directly to the reported operational performance improvement.

Integration Mechanisms between TPM and SMED

Concrete mechanisms were described to ensure the complementarity of TPM and SMED. Integration was achieved through joint diagnostics, coordinated calendars to validate setup changes during maintenance-free windows, and a common information flow to measure availability events and configuration times. Governance adopted periodic data reviews and a small technical committee that prioritized interventions with the highest cost-benefit. Additionally, a feedback cycle was presented whereby problems detected in setups (for example, component wear) triggered planned maintenance actions, and maintenance adjustments that hindered efficient setups motivated new SMED adaptations. This mutual approach allowed improvements in one dimension to facilitate advances in the other.

Operational Adaptation to the Context of the Container-Producing SME

The design considered the usual constraints of an SME: small workforce (15 employees), budget limitations, and dependence on local suppliers. Therefore, low-cost, high-return interventions were prioritized (for example, internal training, tool carts, checklists, and minimum spare parts stock), and a redistribution of roles was proposed to increase operators' multi-skilling. The predefined Schedule and estimated budget (total implementation approximately PEN 20,198.75) were consistent with the company's financial capacity, which facilitated managerial approval and resource allocation. The selection of improvements was supported by an economic impact analysis that showed total losses from low efficiency of PEN 76,109.98 (17% of the annual profit of the 500 ml line), which justified the priority intervention.

Indicator Design, Recording, and Measurement Frequency

The design established simple and operational indicators to monitor model effectiveness: periodic measurements of availability, performance, quality, and setup times, as well as records of stoppages and causes. Capture frequency was set to daily records for critical activities and monthly summaries that fed management reviews. The simplicity of the formats allowed operators and maintenance staff to record data without excessive administrative burden, and monthly results enabled quantification of improvements: OEE rose from 70.76% to 81% during the pilot, availability from 86.76% to 91% and performance from 86% to 93%, data that supported the validity of the design.

Quality Control Mechanisms and Result Verification

Verification routines were incorporated that ran in parallel with TPM and SMED activities. These routines included post-setup inspections to ensure that time reductions did not compromise product conformity, and sampling controls that recorded a quality improvement from 94.49% to 96%. The coexistence of objectives (reducing setup time without losing quality) was managed through acceptance criteria in standardized procedures and with the participation of the quality analyst in improvement teams. The structure ensured that productivity gains were not achieved at the expense of lowered quality.

Training Plan and Skills Development

The detailed design outlined a modular training plan that covered: introduction to TPM and SMED, basic maintenance for operators, standardized execution of setups, and training in data recording. Sessions were scheduled quarterly, and an attendance tracking and competency assessment scheme was established, since training absences had been identified as causes of stoppages (three of six operators with <80% attendance). Training was complemented with short visual material (guides and videos) to facilitate knowledge retention and operational replicability.

Budget, Schedule, and Economic Sustainability

The financial summary of the design integrated costs for training, mechanical tools, consultancy, and teamwork hours. The estimated total budget amounted to approximately PEN 20,198.75, whose comparison with estimated annual losses (PEN 76,109.98) indicated an attractive payback horizon; subsequent financial analysis showed a positive NPV and an IRR that supported investment viability. The operational Schedule was designed to minimize production interference, distributing activities across a four-month window for the pilot phase and scaling according to results. This configuration favored the project's economic sustainability within the SME's limitations.

Follow-up, Audit, and Consolidation Protocols

To mitigate the tendency to revert to previous practices, the design incorporated periodic compliance audits and a consolidation cycle in which internal audits and management reviews assessed adherence to checklists and procedures. The consolidation stage included formative audits, team feedback, and minor procedural adjustments to adapt solutions to real operations. These actions were planned to institutionalize practices and ensure that improvements were sustainable beyond the project team.

Risks, Limitations, and Planned Mitigation Measures

The design recognized risks such as resistance to change, financial constraints, supplier dependence, and demand fluctuations. For each risk, mitigation measures were proposed: demonstrative pilots to build trust, prioritization of low-cost solutions, supply agreements with safety windows for critical spares, and grouping format changes to reduce setup frequencies. Risk management included early-warning indicators (for example, a sudden increase in breakdowns) to trigger rapid maintenance responses. These precautions reduced the likelihood of improvement decay.

Projected impact and operational success criteria

The document linked success criteria to verifiable numerical targets: increase OEE from 70.76% toward the technical objective of 85% (81% was reached during the pilot), raise availability above 90% and reduce setup times by 30–40 minutes for mold changes. These thresholds enabled decision criteria for scaling or adjusting interventions and provided an objective basis for assessing model replicability in other lines or similar firms. Empirical evidence collected during the pilot validated most of the working hypotheses.

Transfer and Replicability Considerations in the Plastics Sector

Finally, the design included guidance for transferring the model to other plants in the sector: prioritize the initial diagnosis, adapt the maintenance plan to local failure profiles, and size training according to staff turnover. It was emphasized that the most replicable improvements were low-cost, high-impact measures (training, standardization, and

small mechanical adaptations) and that orderly data collection facilitated adaptation to different production contexts. The case experience offered an operational framework and a minimum intervention package applicable to SMEs in the industry.

4.4. Results

In Table 1, the quantitative validation of the proposed management model was shown, and its effects on key operational indicators were summarized. OEE increased from 70.76% in the initial condition to 81% in the results, reflecting

a notable improvement in overall equipment effectiveness. Availability rose from 86.76% to 91%, quality improved from 94.49% to 96%, and performance climbed from 86% to 93%, indicating gains in continuity and productive output. Particularly relevant, setup durations were substantially reduced: mold changeover time fell from 96 to 55 minutes (-43%) and temperature calibration time decreased from 52 to 44 minutes (-15%). These outcomes validated the effectiveness of the integrated Lean-TPM approach for the research problem.

Table 2. Validation Results of the Lean-TPM Maintenance Model

Indicator	Unit	As-Is	To-Be	Results	Variation(%)
OEE	%	70.76%	85%	81%	14%
Availability Rate	%	86.76%	94%	91%	5%
Quality Rate	%	94.49%	97%	96%	2%
Performance Rate	%	86%	94%	93%	8%
Setup Time (Mold change)	minute	96	55	55	-43%
Setup Time (Temperature calibration)	minute	52	44	44	-15%

5. Discussion

The results obtained in the current validation closely correspond with numerous documented outcomes in related studies, while also displaying unique characteristics stemming from the model's integrated TPM-SMED design (refer to validation dataset). The rise in OEE from 70.76% to 81% and the significant drop in mold change time are similar to the improvements seen in previous SME-focused interventions: Brizuela-Chauca et al. delineate defect-reduction improvements subsequent to the implementation of Lean tools in PET production [1], while Poves-Calderón et al. document similar enhancements in productivity within a Peruvian plastics SME following integrated Lean-TPM initiatives [11]. The current study's focus on coordinated autonomous and planned maintenance reflects the multi-pillar TPM methodology identified by Lino-Moreno et al. as effective when integrated with SMED and data-driven controls [3]. Daré et al. also show that combining preventive maintenance with lean practices makes equipment more available in small plastics businesses, which is in line with the availability gains we see here [4]. Quispe-Cordova et al. also talk about the practical benefits of combining lean routines with basic maintenance protocols in small plastics operations. This supports the current study's focus on low-cost, high-impact strategies [12]. This work diverges from existing literature by establishing a direct operational linkage between SMED trials and maintenance windows. By scheduling SMED validation during maintenance-free intervals and maintaining a minimal set of indicators, the model achieves rapid changeover compression while ensuring product quality, a balance that has been less frequently evidenced in prior studies. The results confirm that an integrated, resource-sensitive approach to the Lean-TPM pathway yields enhancements that are quantitatively comparable to, and operationally more

replicable than, those delineated in the referenced studies [1], [3], [4], [11], [12].

5.1. Study Limitations

Restrictions. The study is limited by its single-site pilot design, which restricts external generalizability within the diverse population of plastic-bottle SMEs. The intervention period is brief (a four-month pilot phase), limiting the assessment of long-term sustainability and seasonal impacts. Data collection depends on simplified operator logs and regular audits. These tools are intentionally simple, but they may not pick up on subtle quality changes or nuanced failure modes. Limited resources made it impossible to use many instruments (like continuous vibration or thermal monitoring), which would have helped figure out the exact cause of some downtime events. The economic analysis employs prudent cost estimates consistent with the firm's records, yet it excludes wider market fluctuations or supply-chain disruptions that might influence payback periods. Lastly, human factors like changes in behavior and staff turnover are recognized but not quantitatively modeled, which could affect how quickly and how long the gains last.

5.2. Practical Implications

The results have clear, useful effects for managers and workers in small plastics companies. First, focusing on low-cost, high-impact actions (like standardized checklists, tool carts, and quick-release fixtures) lets SMEs with limited budgets make measurable improvements without spending much money. Second, adding self-maintenance tasks to daily routines gives operators the tools they need to find and fix problems before they get worse, which cuts down on minor stoppages and the need for outside technicians. This speeds up repairs and makes the shop floor more responsive. Third,

scheduling SMED trials to coincide with maintenance windows keeps production windows open and allows for reliable validation of changeover improvements, which reduces friction between experiments and operations. Fourth, a short set of indicators (changeover time, short stop counts, checklist compliance, and monthly OEE snapshots) strikes a balance between managerial oversight and practicality. This lets small management teams keep making improvements without getting too much work done. In practice, the model supports gradual scale-up: pilot wins provide clear proof that management can use to get small follow-on investments (spares, simple fixtures) and to make routines official through short training modules and visual aids.

5.3. Future Works

Work in the future. The next step in the research agenda should be to look into multi-site replication to see if it works for firms of different sizes, machine ages, and product mixes. Subsequent research should broaden the observational scope to assess the sustainability of behavioral modifications and the impact of employee turnover on the continuity of Key Performance Indicators (KPIs). Adding low-cost condition monitoring tools like portable vibration kits and thermal cameras would make predictive maintenance triggers more precise and help figure out what caused downtime in more detail. Experimental designs that randomize SMED interventions across similar lines could enhance causal inference concerning changeover strategies. Economic modeling must be expanded to incorporate sensitivity analyses for fluctuations in raw material prices and disruptions in supplier lead times. Lastly, turning the model into a simple digital toolkit (like mobile checklists and simple dashboards) and testing the barriers to adoption would make it easier to

share across the sector and make it easier to do future comparative research.

6. Conclusion

The study presents empirical findings that demonstrate significant operational improvements following the implementation of the integrated Lean-TPM model on the blow-molding line: Overall Equipment Effectiveness (OEE) increased from 70.76% to 81%, availability rose from 86.76% to 91%, performance climbed from 86% to 93% and quality improved from 94.49% to 96%. Critical times were also substantially reduced, with mold changeover time falling from 96 to 55 minutes (-43%) and temperature calibration from 52 to 44 minutes (-15%), yielding a partial recovery of lost time and a reduction in estimated losses of PEN 76,109.98, equivalent to 17% of the annual profit of the 500 ml line. This evidence is meaningful: low-cost, targeted interventions increase SME competitiveness by reducing bottlenecks, cutting losses, and improving the indicators that govern production and delivery. The main contribution lies in a replicable operational framework that integrates autonomous maintenance, planned maintenance, and SMED within coordinated windows, supported by simple records; this design enables impact measurement on availability, performance, and quality without requiring substantial technological investment and facilitates adoption by resource-constrained firms. Finally, it is recommended to pursue multi-site validations and longer time horizons to certify the changes' durability, incorporate affordable condition-monitoring, perform sensitivity analyses against input variability, and develop a digital and training package that eases regional replication across the industry.

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