Frugal Digital Transformation to Increase Operational Availability in HDPE Pipe Extrusion: SMED 4.0 with Human Centricity and Predictive Maintenance

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Abstract*— The low operational availability of continuous extrusion processes limits the competitiveness of manufacturing SMEs in the plastics sector. In a Peruvian HDPE pipe plant, high set-up times and mechanical failures reduce availability to 81.46 % and generate annual losses of S/ 247 026. The literature addresses both problems in isolation and usually relies on costly IoT sensing, which is hardly viable in environments with limited instrumentation. This work proposes an integrated digital transformation model with a Human Centricity approach that combines an intelligent SMED 4.0 set-up system (with RFID identification, digital recipes and visual assistance to the operator) and predictive maintenance based on machine learning over the already available historical failure records, configuring a low-cost frugal innovation solution. The model is validated through discrete-event simulation and a computational prototype on the extruder of line L3. The evaluation projects a 50.53 % reduction in set-up time, a 25.59 % decrease in mechanical failures and an increase in availability to 88.51 %, with an NPV of S/ 141 688 and a payback of 1.58 years. The model closes 82 % of the gap to the world-class benchmark and offers a potentially transferable digital transformation route to strengthen the competitiveness of regional manufacturing without large investments in sensing.

Keywords: machine learning; predictive maintenance; frugal innovation; SMED 4.0; Human Centricity

I. Introduction

Global plastics production reached 413.8 million tonnes in 2023, an increase of 43.1 million over 2018 [1]. This behavior confirms the economic relevance of the sector across various productive activities, as well as the need to improve productive efficiency in light of the growing concern for sustainability and the limited substitution by circular materials, which barely represent 9.6 % of production [1].

At the national level, the Peruvian plastics sector contributed 3.7 % of manufacturing GDP and 2 661 million soles in 2024, with 5.5 % growth driven by rising demand [2]. However, 64 % of firms operate between 61 % and 70 % of their installed capacity and only 11 % reach optimal levels of 91 % to 100 % [3], compared with rates above 80 % reported in developed countries [4]. This underutilization reflects the persistence of obsolete machinery, the 26.5 % informality of the sector [2] and the low adoption of digitalization technologies, which positions operational availability as the critical indicator of the problem. Beyond the operational diagnosis, this gap poses a challenge of technological capability development and competitiveness for manufacturing SMEs in emerging economies.

Operational availability is one of the components of *Overall Equipment Effectiveness* (OEE) most affected in extrusion and continuous manufacturing processes, where the uninterrupted nature of the process turns each stoppage into an unrecoverable loss. Recent literature reports systemic availabilities as low as 57.79 % in plastics-sector lines in Greece [5] and modified-OEE measurements between 11.07 % and 54.65 % in a polymer extrusion line in India [6], far below the world-class benchmark of 90 % in availability [7] and 85 % in OEE [8].

In light of this scenario, two main lines of response have been developed, supported by digital transformation and other Industry 4.0 trends: (i) SMED 4.0 with digital technologies and a Human Centricity approach to reduce format changeover times [9] and (ii) predictive maintenance to anticipate failures and reduce unplanned stops [10].

These initiatives, applied mostly across various industrial sectors, have documented set-up time reductions between 48 % and 72 % [11], [12], OEE increases close to 10 % [13] and reductions of unplanned stops between 25 % and 45 % [14], [15].

Despite the reported methodological maturity, two gaps persist that hinder the direct application of these results to continuous polymer extrusion. First, existing contributions operate in isolation: SMED 4.0 focuses on reducing changeover time and predictive maintenance concentrates on unplanned stops, without a common framework linking both components in an integrated proposal [16]. Second, artificial-intelligence-based predictive maintenance applications within plastics manufacturing concentrate on injection molding [17], whereas continuous extrusion exhibits distinct degradation patterns whose predictive response has not yet been quantified in the literature.

The objective of this work is to increase the operational availability of a continuous HDPE pipe extrusion process through an integrated model that combines an intelligent set-up system based on SMED 4.0 (with RFID identification and standardized digital recipes) and a Human Centricity approach, and a predictive maintenance component grounded in statistical and machine learning models over the historical stop and failure records, configuring a low-cost frugal innovation solution. The Human Centricity approach is incorporated into the SMED 4.0 component through the ergonomic design of the set-up workstation, visual instructions and the operator's participation in verifying critical process parameters.

The remainder of the article is organized as follows. Section II presents the literature review classified by typologies. Section III describes the proposed model and its components.

Section IV details the problem-analysis and validation methodology. Section V presents the results obtained. Section VI discusses the results against previous studies. Finally, Section VII presents the conclusions, limitations and future work.

II. Literature Review

Operational availability in extrusion and continuous manufacturing processes

Operational availability is one of the most critical indicators in extrusion and continuous manufacturing processes, where the uninterrupted nature of the flow turns each stoppage of the main asset into a volume loss that cannot be recovered. The literature that measures OEE and its components in these environments consistently documents availabilities and efficiencies well below the world-class benchmark, which sets availability above 90 % and OEE close to 85 % [8].

The reviewed works agree on two families of root causes. The first is variability in start-ups, format changeovers and process parameters: in a polymer extrusion line, the waste associated with format changeover concentrated the largest share of losses, above start-up losses and power outages [6]. The second is the concentration of failures in a few critical assets: in a plastics manufacturing line, 80.7 % of failures originated in a single machine and 99.3 % in the three most critical ones, which confirms the Pareto principle and directs the intervention toward the main asset [5].

The documented interventions combine maintenance and continuous-improvement tools on the main asset. The application of TPM pillars together with 5S in a continuous line raised availability from 89.92 % to 91.62 % and OEE from 65.59 % to 68.12 %, freeing up additional capacity [7], whereas a scheme based on DMAIC with Kaizen and cause-effect diagrams brought critical machines closer to the world-class benchmark [8]. A substantial part of these improvements does not come from technology alone, but from organizational measures such as operator training, updating work instructions and the periodic review of process parameters [7].

The processes covered by this literature share with thermoplastic polymer extrusion the condition of being a continuous process, the dependence on a main asset and the sensitivity of availability to both format changeovers and failures. This equivalence supports the applicability of the reviewed findings and organizes the two lines of response developed in the following subsections: the reduction of set-up times and the mitigation of unplanned stops.

SMED 4.0 with a Human Centricity approach for the reduction of set-up times

The SMED 4.0 line integrates the classical methodology with sensors, predictive models and decision matrices. The Set-up Saving Deployment, based on three matrices that quantify set-up losses, evaluate corrective actions and rank them by cost and effectiveness, achieved a format changeover time reduction from 1 070 s to 210 s (72 %) [11].

Likewise, the addition of an extra stage to classical SMED, called Performing Online Setting, supported by IoT sensors and a multiple linear regression model with a predictive accuracy of 0.99, reduced the defect rate in polyurethane injection from 3 % to 0.2 % and delivered a 93 % improvement in the Triple Bottom Line criteria (economic, social and environmental sustainability) [9]. The Sustainable Setup Stream Mapping, which integrates SMED with value-stream mapping, achieved annual savings close to USD 255 000 [18].

For its part, a vertical lathe was upgraded through retrofitting with PLC, position transducers and IO-Link sensors integrated with SMED and PDCA, starting from an initial OEE of 52 % and a downtime due to corrective maintenance of 89.6 %. As a result, manual adjustments were replaced by preconfigured recipes in the controller [19]. The integration of fuzzy FMEA with SMED on plastic injection machines achieved a 48 % reduction in changeover time [12].

The review points to two consistent findings. First, approaches that enhance classical SMED with digital technologies and structured matrices reach reductions of 48 % to 72 % in set-up time [11], [12]. Second, digital technologies such as IoT only add value when combined with structured Lean practices, evidence supported by a study of 440 operators across 33 Italian plants showing that the isolated introduction of IoT negatively moderates the relationship between work engagement and problem solving; only when IoT is coupled with Lean practices does this relationship become positive [20].

A systematic review of the Operator 4.0 concurs that this figure remains in an immature phase because the technological offering of Industry 4.0 does not yet sufficiently integrate the human factor [16]. These results justify the design of a SMED 4.0 with a Human Centricity approach rather than an isolated technological deployment.

The Human Centricity approach places the operator at the center of the design of digital production systems and accompanies the transition from Industry 4.0 toward Industry 5.0 and the Lean 5.0 paradigm. The Lean 5.0 framework, built from two Italian leather-goods cases, shows that human-centered practices are enhanced by Industry 4.0 technologies rather than displaced by them [21].

A recent review of Human-Centred Design in Industry 4.0 concludes that the published efforts are numerous but do not articulate with one another, so that person-centered design must be the axis of future smart manufacturing [22]. The Human-Cyber-Physical Systems framework places the operator within the cyber-physical system through augmented reality, a human digital twin and ten core characteristics aimed at reorganizing smart manufacturing from a person-centered perspective [23].

The application of this logic in a metalworking company, through the integration of SMED with ergonomic methods (REBA, RULA, JSI, KIM and the Shoaf model), reduced format changeover by 55 %, increased monthly output by 26.4 % and lowered the risk of musculoskeletal disorders from "very high" to "acceptable" [24]. The Respect for

People model, formed by two parallel value streams, that of the product and that of people, sustains continuous improvement only when both advance together [25].

The review confirms that the human factor is a central criterion in the technical decisions of SMED 4.0 and that its omission erodes Lean results in the medium term [20]. The Lean 5.0 [21], Human-Cyber-Physical Systems [23] and Respect for People [25], frameworks, together with the ergonomic methods REBA, RULA, JSI, KIM and the Shoaf model [24], operate as cross-cutting human criteria in the design of the proposed model.

The integration of these criteria with digital technologies and Lean tools makes it possible to close the gap identified by the literature between the technological advance of Industry 4.0 and the maturity of the Operator 4.0 [16], which supports the relevance of the model with a Human Centricity approach proposed in this article.

Predictive maintenance for the reduction of unplanned stops

Predictive maintenance based on statistical and machine learning techniques constitutes one of the most active pillars of Industry 4.0 in recent literature. A recent classification of predictive maintenance highlights the contributions of data analytics and artificial intelligence to the maintenance cycle [10].

A first line of work installs sensors on critical assets: IntelliPdM, an edge-cloud platform with six wireless vibration sensors and an ensemble of algorithms whose Random Forest reached an accuracy of 0.9901, delivered over twelve months reductions of 35 %–45 % in downtime, 70 %–75 % in breakdowns and 25 %–30 % in maintenance costs, with a tenfold ROI on the investment [14]; a predictive architecture based on wireless vibration and temperature sensors with an ANN model trained in TensorFlow increased the effective capacity of the equipment in an SME [26].

A second line, aligned with industrial environments where sensing is limited, models failure risk from the historical stop and maintenance records. The combination of survival functions with Simulated Annealing over historical data achieved a 25 % reduction in downtime [15], while inspections scheduled according to the remaining useful life of the equipment reduced total maintenance costs by 5.5 % [27].

Other contributions extend the method with uncertainty quantification and reinforcement learning under a conservative criterion [28] and with anomaly detection on rotating equipment in generation plants [29].

The review identifies three patterns that guide the design of the predictive component. First, tree ensembles such as Random Forest and XGBoost [14], deep neural networks such as ANN, CNN and LSTM [26] and survival analysis [15] make up the core methodological repertoire, with accuracies above 0.98 when the datasets are representative.

Second, the line based on historical failure records is especially suitable for productive environments with limited instrumentation, since it operates on data already available in the maintenance areas and dispenses with additional investments in sensing [15].

Third, the applications reported in plastics manufacturing concentrate on injection molding [17], whereas continuous polymer extrusion, with distinct operational dynamics, constitutes a gap in the state of the art that this article contributes to filling with empirical evidence.

III. Proposed Model

A. Rationale

The proposed model is grounded in three articles that define its technical pillars and orient each component toward specific technological trends analyzed in the literature review. Khakpour's SMED 4.0 [9] provides the conceptual framework of Component 1, particularly the articulation of classical SMED with digital identification of tooling and visual assistance to the operator, which materializes digital transformation through the Internet of Things.

The proposal by Fonda and Meneghetti [30] places the operator at the center of format-changeover standardization and defines the ergonomic, cognitive and training criteria that support the Human Centricity trend of the model, which translate into the visual checklist, the training plan and the design of guards for the new preparatory activities.

Coutinho's modular approach [15], which articulates survival analysis with optimization techniques over historical records, underpins the architecture of Component 2 and materializes the trend of predictive analytics based on historical data through a segmentation by sub-cause with automatic selection of the optimal forecasting algorithm. The integration of these three anchors allows each component to address a specific root cause of the problem without losing the coherence of the proposed integrated model.

B. Proposed model

The contribution is conceived as a model that integrates two complementary components: an intelligent set-up system under a Human Centricity approach, combining SMED 4.0 with RFID identification, digital recipes and visual assistance to the operator (Component 1), and predictive maintenance management based on the analysis of historical failure records through statistical and machine learning techniques (Component 2). The novelty of the model is embodied in three elements.

First, the implementation of Industry 4.0 technologies over the classical SMED methodology (RFID identification of tooling, digital recipes on a low-code platform and a Modbus TCP link with the control panel), industrial digital transformation over a traditional Lean tool. Second, as an expression of frugal innovation, the substitution of IoT sensing of the asset by a modular predictive model fed by the historical records already available in the maintenance areas, which reduces the adoption cost and the implementation barriers in SMEs and productive environments with limited instrumentation.

Third, the integration of the Human Centricity approach over the SMED 4.0 component through the ergonomic design of the set-up workstation, visual instructions and the operator's participation in verifying critical parameters, an articulation not reported in the literature on the Operator 4.0 [16] nor in the Lean 5.0 frameworks [21]. Fig. 1 presents the conceptual model.

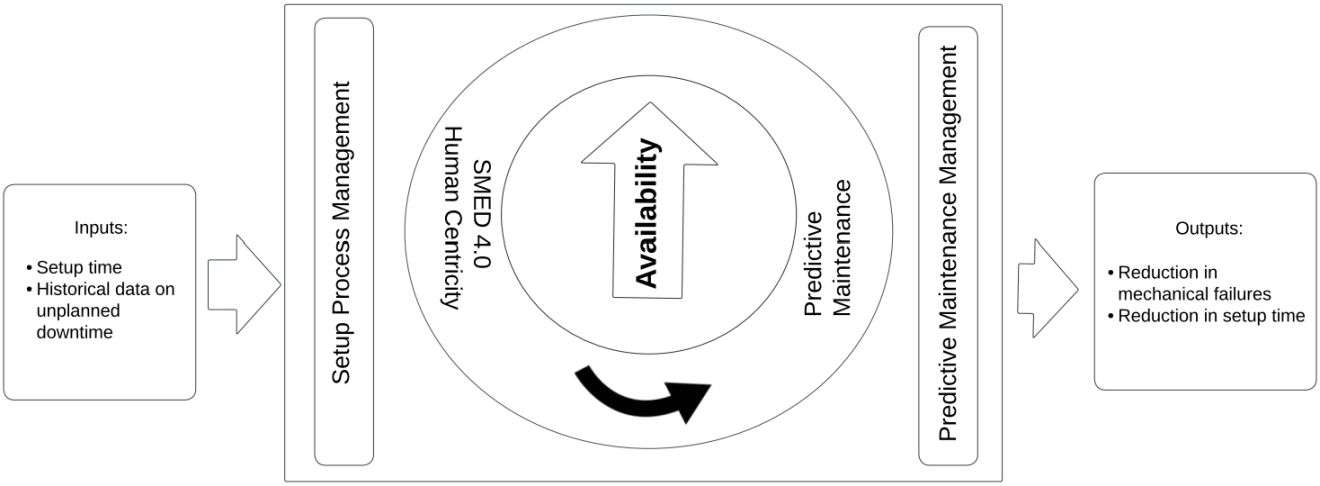


Fig. 1. Conceptual model of the proposal with a Human Centricity approach.

C. Model detail

General description of the process. The model is executed through two parallel flowcharts that share the final monitoring phase. Component 1 follows three successive blocks: system preparation (time study, internal/external classification and consolidation of information), SMED application (separation of activities, conversion of internal into external ones and time reduction), and standardization under a Human Centricity approach following the framework of Fonda and Meneghetti [30].

Component 2 is executed in three sequential blocks: data preparation (capture through a standardized form, consolidation in a master database and selection of the highest-weight sub-cause), execution of the predictive method (automatic selection of the optimal forecasting method and estimation of the daily failure probability through a hybrid classifier), and system implementation (deployment of the web application with a heat map by sub-cause).

Fig. 2 and Fig. 3 present the flowcharts of Component 1 and Component 2, respectively.

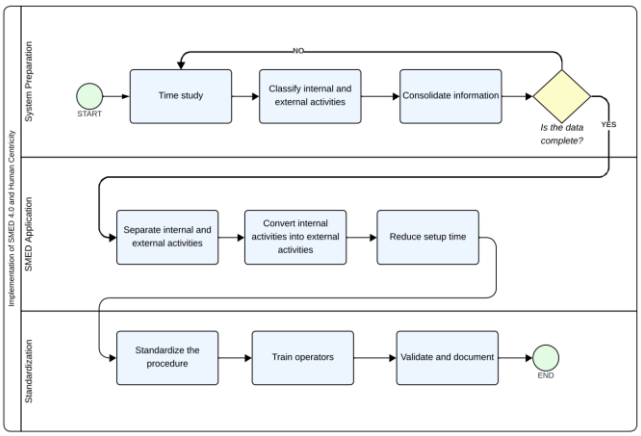


Fig. 2. Implementation flowchart of Component 1 (SMED 4.0 and Human Centricity).

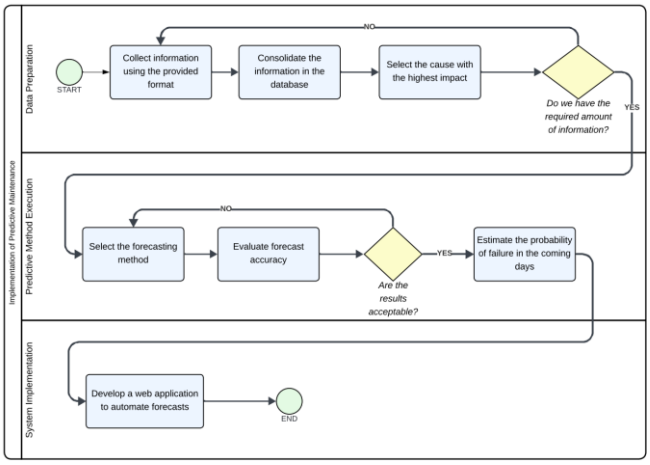


Fig. 3. Implementation flowchart of Component 2 (predictive maintenance).

Specific description of the artifacts. The model is divided into six artifacts classified according to their function within the data flow. The input instruments collect process information; the transformation ones process it; and the decision-making ones deliver it to the user in an actionable form.

(i) Format-changeover time-study form: a standardized form on a digital spreadsheet that breaks down the sixteen sequential set-up activities, measures their duration through direct timing and classifies them as internal (IED) or external (OED) depending on whether or not they require the machine to be stopped. Its purpose is to serve as a quantitative input for prioritizing convertible activities and for the baseline of the simulation model.

(ii) Incident-record form: a weekly standardized form that documents each unplanned stop with date, affected line, start and end time, root cause, event type and qualitative description. Its purpose is to feed the master database of

Component 2; it constitutes the only data input of the predictive prototype and therefore the critical artifact for the traceability and coverage of the system.

(iii) Digital recipe sheet: an application developed on the low-code platform Microsoft Power Apps, accessible from an industrial tablet next to the extruder. It centralizes the parameters of each format (diameter, SDR, temperatures and speeds), delivers them organized to the operator and automatically times each activity through a Modbus TCP link with the control panel. Its purpose is to eliminate the manual re-entry of parameters and the dependence on the operator's memory during set-up.

(iv) Modular hybrid forecasting model: a computational component located on the cloud server of the predictive application, which evaluates each sub-cause against four candidate methods (Simple Exponential Smoothing, Holt, Holt-Winters and ARIMA(1,1,1)) and automatically selects the one with the lowest RMSE in walk-forward validation, complemented by a hybrid classifier (LightGBM, Random Forest or logistic regression with model calibration) whose algorithm is assigned according to the historical frequency of events. Its purpose is to estimate the daily failure probability by sub-cause over a thirty-day horizon without requiring additional instrumentation on the asset.

(v) Visual format-changeover checklist: a dual support deployed simultaneously on the industrial tablet and on a laminated A3 sheet fixed to the workstation, with two clearly delimited blocks: a preparatory block (T−60 to T0) with the machine running, executable externally, and a stop block (T0 to T+125) with the machine stopped, executable internally. Its purpose is to guide the operator step by step, reduce cognitive load during format changeover and materialize the Human Centricity criteria defined by Fonda and Meneghetti [30].

(vi) Predictive management software: a web application developed in Python with the Streamlit library, hosted on an AWS EC2 cloud server, which processes the operational database, runs the algorithms of the modular model and delivers as output a heat map by sub-cause with the daily probability of occurrence over a thirty-day horizon, as well as the schedule of suggested preventive maintenance. Its purpose is to enable the Maintenance Department to plan interventions in advance according to the criticality of each component, transforming historical records into actionable information.

D. Model Indicators

The impact of the model is measured through three indicators: two of time, directly associated with the components, and one integrating outcome. The set-up time measures the monthly accumulated duration of the extruder's format changeovers (in hours/month); it is obtained from the information recorded by the digital recipe sheet (artifact iii) and acts as a direct variable of the impact of Component 1.

The mechanical-failure time measures the monthly accumulated duration of unplanned stops attributable to failures in the thermal and drive systems (in hours/month); it is obtained from the incident-record form (artifact ii) and acts as a direct variable of the impact of Component 2. Operational availability integrates both components and is computed as $D = (TT - TP) / TT \times 100$, where TT is the total available time and TP is the sum of the set-up times, mechanical failures and other process stops; its target is to reach the world-class benchmark ≥ 90 % [7]. The measurement is carried out monthly over the operational records of the line and makes it possible to build the As-Is vs. To-Be comparative tables of the validation phase.

IV. Methodology

A. Problem Analysis (As-Is)

The problem analysis was carried out on the historical stop records of line L3 during the 2025 period. The diagnosis applied a criticality analysis over the lost times of the plant's four lines, which identified L3 and its extruder as the focus of the problem, and a problem tree that identified the root causes, complemented by a format-changeover time study. Within set-up, the change of size and tooling explained 49.64 % of the lost time and the configuration of parameters 8.68 %, while unplanned stops were attributed to failures of the thermal and drive systems, which defined the scope of Component 2. The sources of unavailability were classified, their frequency and accumulated duration in hours per year were quantified, and their annual economic impact was estimated, in order to establish the baseline against which the proposal is evaluated.

B. Validation Method (To-Be)

The selection of the validation method responds to the distinct nature of the two components of the model. Component 1 acts directly on the duration of the format changeover, but its operational impact is projected onto systemic indicators, availability, total cycle time and intermediate inventory between stages, which cannot be reliably estimated from the isolated observation of the changeover activity.

For this reason, discrete-event simulation is adopted, a method recurrently reported in the literature to evaluate SMED configurations under controlled conditions and with sufficient replications to build statistically significant confidence intervals without intervening in the asset in operation [12].

Component 2 represents a contribution of a computational nature, embodied in statistical and machine learning models, a visualization module and a decision logic, whose performance must be verified before deploying the system in the plant.

For this reason, prototype validation is adopted, a predominant practice in the literature for modular industrial predictive systems [15], [16]. Both methods avoid the operational interruption that a physical pilot would demand and allow sensitivity analyses to be run with statistically significant replications.

Case study. The validation was carried out on extrusion line L3, equipped with a QH200 extruder, belonging to a Peruvian

HDPE pipe production plant in the plastics sector, during the 2025 period. The line processes virgin HDPE resin with an average output of 114.12 kg/h and operates continuously.

The format-changeover process constitutes the main source of unproductive time of the asset and is based on a sequence of sixteen operational activities. The scope of Component 2 was restricted to the Thermal and Drive Systems of the extruder, which concentrate more than 80 % of the asset's unplanned stop hours and have sufficient event density for reliable statistical calibration.

Execution of Component 1. The validation of Component 1 was carried out through discrete-event simulation in Simio, reference software for manufacturing environments [12]. The construction of the computational model followed the seven phases recommended by the literature: collection and statistical characterization of the input data, elaboration of the conceptual model, construction of the computational model, verification, validation against historical behavior, definition of scenarios and execution of the runs.

The time study identified sixteen sequential format-changeover activities (A01 to A16) with an average duration of 251.75 min/event, a value consistent with the annual history. The variability of each activity was modeled through a triangular distribution ±15 % around the mode, an assumption consistent with the practice reported for Lean simulation studies where a reliable mode obtained by direct timing is available. The To-Be scenarios evaluate the system-level effect of the defined activity times following SMED conversion and task redesign, rather than independently establishing the causal effect of each digital aid.

Event arrivals were modeled through an exponential distribution with a mean of 2 345 min, derived from the history of approximately 19 monthly changeovers. The model was run over a horizon of 365 days with 30 independent replications per scenario and a 95 % confidence level. The cross-validation of the As-Is scenario yielded 944.42 h of set-up against the 949.63 h of the history, with a difference of 0.55 %, well below the 10 % threshold accepted by the literature to consider a discrete-event model validated [12], [20].

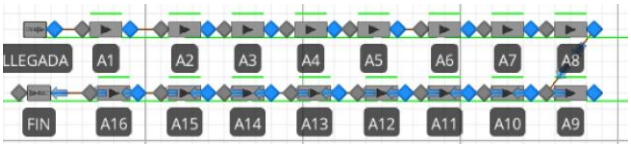


Fig. 4. Discrete-event simulation model of the format changeover in Simio (Component 1).

Execution of Component 2. The validation of Component 2 was carried out through a computational prototype developed in Python with the scikit-learn, lightgbm, statsmodels, pandas and Streamlit libraries, following a modular architecture composed of three functional blocks (data processing, predictive engine and visualization), a criterion reported in the literature for industrial predictive systems that require maintainability and scalability [15].

The scope was restricted to the Thermal and Drive Systems of the extruder, in which seven critical sub-causes were identified and 104 failures accumulated during 2025 (75 thermal and 29 drive).

The predictive engine applies a modular Thermal and Drive strategy by sub-cause: each sub-cause has its own monthly forecasting model of lost hours, automatically selected among four candidates (Simple Exponential Smoothing, Holt, Holt-Winters and ARIMA(1,1,1)) according to the method that minimizes the RMSE in walk-forward validation, and its own daily hybrid classifier (LightGBM, Random Forest or logistic regression with model calibration) assigned according to the historical frequency of events.

The 2025 period was evaluated retrospectively using a monthly walk-forward scheme initialized with the 2021–2024 records: for each month of 2025, the model predicted the daily probability of occurrence of each sub-cause using only information available up to the previous month.

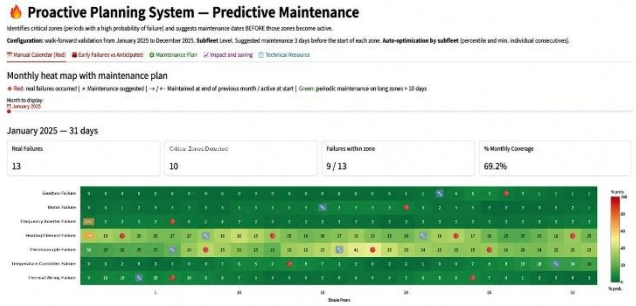


Fig. 5. Interface of the predictive management software: monthly heat map by sub-cause (Component 2).

V. RESULTS

A. Results of the problem analysis (before)

Initial diagnosis (As-Is). The operational diagnosis of the 2025 period evidenced an average operational availability of 81.46 %, a value below the world-class benchmark of 90 % [7]. Stops are concentrated mainly in two sources: format changeovers, which accumulate 949.63 h/year (58.32 % of total stops), and mechanical failures, which accumulate 544.65 h/year (33.45 %). The remainder (8.22 %) corresponds to minor stops not attributable to the components of the proposal.

The economic impact associated with the current state amounts to S/ 247 026 per year, calculated from the total loss per stop hour of S/ 151.73, made up of the loss of unproduced raw material (USD 37.66/h) and the idle labor cost of the two direct operators (USD 6.41/h). Table 1 summarizes the initial diagnosis over the model indicators.

Table 1. Initial diagnosis of line L3 over the model indicators

Indicator	As-Is	% Non-operating time
Set-up	949.63 h/year	58.32 %
Mechanical failures	544.65 h/year	33.45 %
Other stops	133.90 h/year	8.22 %
Availability	81.46 %	—

B. Results of the Validation (after)

Results of Component 1 (SMED 4.0). Under the moderate scenario (100 % compliance with the project specification), the simulation reports that the average format-changeover

time decreases from 252.97 to 125.14 min/event, equivalent to a 50.53 % reduction. The annual accumulated set-up hours drop from 944.42 to 467.19 h. Under the pessimistic scenario, in which only 80 % of the expected saving is achieved, the average time stands at 141.05 min/event, which still represents a 44.24 % reduction. Under the optimistic scenario (120 % effectiveness), the average time stands at 109.22 min/event, equivalent to a 56.82 % reduction.

Table 2 presents the results with their 95 % confidence intervals; the absence of overlap between the intervals confirms that the three levels are statistically distinguishable ($p < 0.05$).

Table 2. Results of the Component 1 simulation by scenario with 95 % confidence intervals

Scenario	Time (min)	Reduction
As-Is	252.97	—
Pessimistic	141.05	44.24 %
Moderate	125.14	50.53 %
Optimistic	109.22	56.82 %

Results of Component 2 (Predictive maintenance). The predictive maintenance prototype, applied to the 104 critical failures of the 2025 period, achieved a combined coverage of 47.1 %, an operational efficiency of 68.6 % and an estimated annual benefit of 139.40 h, equivalent to 32.5 % of the 428.93 h of critical attackable failures of 2025 and to 25.59 % of the line's total mechanical-failure time (544.65 h/year).

The system generated 86 suggested preventive maintenances, of which 59 matched a recorded failure within their operational window. The breakdown by physical module reveals a differentiated behavior: the Drive System reaches a lift of 1.84× with a point coverage of 65.5 %, a result consistent with the greater predictability of mechanical failures due to their more regular mean times between failures, whereas the Thermal System stands at 1.40× with a coverage of 34.2 %, consistent with the more stochastic nature of thermal failures, dependent on factors such as polymer composition and operating cycles.

Table 3 presents the reduction of stop hours of the prototype by physical module.

Table 3. Reduction of stops by physical module

Module	Reduction
Thermal	21.5 %
Drive	36.1 %
Total	32.5 %

As-Is vs. To-Be over the model indicators. The contrast between the model indicators and the initial diagnosis quantifies the integrated impact of the proposal. Table 4 summarizes the As-Is vs. To-Be comparison over the three indicators defined in subsection III.D. The joint reduction of the attackable hours, from 1 494.28 to 875.02 h/year, is equivalent to 41.27 % of the total operational problem, which translates into an increase in the projected operational availability from 81.46 % to 88.51 %, that is, +7.05 percentage points, a value that brings line L3 closer to the world-class benchmark of 90 % [7] and is within the maximum range reported in the literature for combined SMED 4.0 + predictive maintenance implementations [9], [26].

Table 4. As-Is vs. To-Be comparison over the model indicators (realistic scenario)

Indicator	As-Is	To-Be
Set-up (h/year)	949.63	469.77
Mechanical failures (h/year)	544.65	405.25
Operational availability	81.46 %	88.51 %

C. Economic Impact of the Project

The economic impact assessment of the project was carried out over a five-year horizon, aligned with the effective useful life of the digital assets identified in the budget and consistent with the usual practice in Industry 4.0 projects. The construction of the free cash flow required the definition of four groups of variables: the current economic impact of the line diagnosed, the expected benefits by component, the initial investment concentrated in Year 0 and the recurring operating expenses (OPEX) needed to sustain the solution.

The financial parameters of the flow assume a cost of capital of 13.5 %, computed through CAPM adjusted for emerging markets, an income tax rate of 29.5 % in accordance with the Peruvian general regime, and an annual inflation rate of 3 % equivalent to the upper limit of the target of the Central Reserve Bank of Peru for the 2026-2030 period. The initial investment amounts to S/ 65 537 without VAT, distributed between Component 1 with S/ 38 733 and Component 2 with S/ 26 804.

The profitability indicators computed over the free cash flow are presented in Table 5. The Net Present Value amounts to S/ 141 688, which means that the implementation creates economic value above the cost of capital required by the company. The Internal Rate of Return of 85.36 % greatly exceeds the cost of capital of 13.5 %, offering a margin above 71 percentage points that confirms the profitability of the project even under variations in the cost of money.

Table 5. Economic profitability indicators of the project

Indicator	Value	Criterion
NPV	S/ 141 688	Meets
IRR	85.36 %	Meets
B/C	3.74	Meets
ROI	460.64 %	Meets
Discounted payback	1.58 years	Meets

A complementary reading of the flow evidences the dynamics of progressive mitigation of the diagnosed economic impact. The model mitigates approximately 37.88 % of the annual economic impact of the line in steady state and closes 82.00 % of the technical gap to the world-class benchmark of 90 % availability.

Finally, the 133.90 annual hours corresponding to structural stops fall outside the technical scope of the model's components and constitute an unrecoverable loss floor with the present proposal.

D. Non-economic Impact of the Project

Beyond the economic indicators, the proposal generates non-economic effects on three assessable dimensions: the physical environment of the process (environmental impact), the cognitive conditions of the operator (social and labor

impact) and the level of digitalization of the plant (technological impact). These effects require specific evaluation methods and receive differentiated treatment in the following paragraphs.

1) Environmental impact

The evaluation Matrix through the Conesa Importance [31] identified fourteen significant interactions, thirteen positive and only one negative, corresponding to the future generation of WEEE from the digital equipment, classified as compatible (Importance −21) and contemplated in the economic flow. The positive effects of greatest importance correspond to staff training (+40 in training and employment, +38 in occupational health and safety) and to the operation of both components (+32 and +29). No interaction reaches the severe or critical classification, which confirms the environmental viability of the project.

2) Social and labor impact

Through the integrated HTA-CLT-TACOM approach [32] – [33], the cognitive complexity index of the format changeover is reduced by 43.4 % (from 2.88 to 1.63), with drops of up to 57 % in the sub-measures of information, decision, abstraction and logic, and a more moderate reduction (16.8 %) in size, consistent with the preservation of the number of activities. The improvement is attributed to the Human Centricity redesign (digital identification of tooling, visual checklist, ergonomic improvements and training plan) that acts on the extraneous cognitive load of the procedure [30], [34].

3) Technological impact

The acatech Industrie 4.0 Maturity Index [35] reports an average advance of 2.00 levels (from 1.50 to 3.50 out of 6), driven mainly by the Information Systems area (from 1.0 to 4.5), which positions line L3 in the Transparency stage with progress toward Predictive Capability. The target state of 3.50 exceeds the averages reported in recent empirical evaluations of the model (2.49–2.91), which supports the technological ambition of the proposal within the evaluated scope.

Fig. 6 presents the As-Is vs. To-Be radar diagram over the four structural areas of the acatech, a format recommended by the model to visualize the digital transformation achieved.

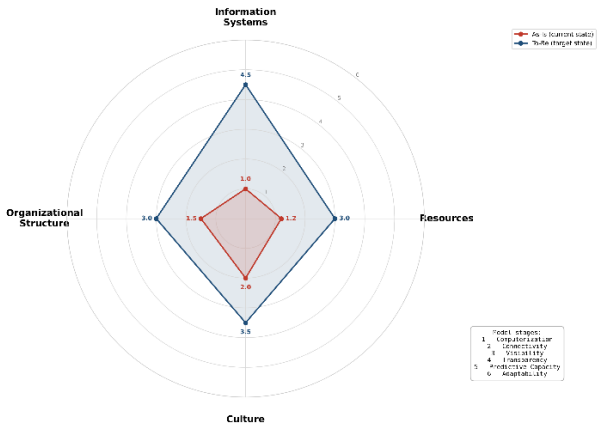


Fig. 6. Radar diagram of digital maturity As-Is vs. To-Be (acatech).

VI. Discussion

A. Comparison of the Initial State and the Evaluated State

The evaluation projects the performance of line L3 over the three diagnosed indicators. Set-up, which in the initial state concentrated 949.63 h/year, is reduced to 469.77 h/year, and mechanical failures drop from 544.65 to 405.25 h/year, which raises operational availability from 81.46 % to 88.51 %, an increase of 7.05 percentage points that closes 82 % of the gap to the world-class benchmark of 90 %. In economic terms, this leap turns an annual loss of S/ 247 026 into a project with an NPV of S/ 141 688 and a payback of 1.58 years. The contrast between As-Is and To-Be confirms that the combination of both components simultaneously attacks the two main sources of unavailability identified in the diagnosis.

B. Analysis of Results Against the Literature

The results of Component 1 lie within the upper range of the benchmark reported by the specialized literature for SMED 4.0 implementations. The 50.53 % reduction in changeover time under the moderate scenario exceeds the 48 % obtained by the integration of fuzzy FMEA with SMED on plastic injection machines [12] and approaches the 55 % of the metalworking case with integrated ergonomic methods [24].

The results of Component 2 lie in the low-medium zone of the international range for industrial predictive systems. The 32.5 % reduction under the realistic scenario falls within the 25 %–55 % range reported by empirical studies [14], [15] and converges with the 25 % obtained by the modular approach based on survival analysis with optimization techniques [15], a direct reference for the proposed model.

The closing of the technical gap of 82 % to the world-class benchmark of 90 % operational availability lies within the maximum range reported in the literature for combined SMED and predictive maintenance implementations [9], [26], which validates the order of magnitude of the integrated contribution and supports the relevance of the model for the Peruvian industrial context of the plastics sector, as well as its potential for scalability and replicability as a frugal digital transformation route for manufacturing SMEs.

C. Closest Related Work

Among the reviewed literature, three works constitute the closest pillars to this proposal, one for each component of the model. The first, Khakpour's SMED 4.0 [9], provides the conceptual framework of Component 1 by articulating classical SMED with digital identification of tooling and visual assistance to the operator; its merit is to demonstrate the viability of a digital set-up, and its relationship with this work is direct, with the difference that [9] concentrates on reducing set-up defects and does not integrate predictive maintenance nor quantify the impact on operational availability. The second, Coutinho's modular approach [15], underpins Component 2 by modeling failure risk through survival analysis and optimization techniques over historical records, achieving a 25 % reduction in downtime; its merit is

to dispense with embedded sensing, and it shares with this proposal the frugal basis of already available historical data. The third, Gladysz's systematic review of the Operator 4.0 [16], supports the Human Centricity approach by evidencing that the technological offering of Industry 4.0 does not yet sufficiently integrate the human factor; its contribution is to delimit that gap, and its relationship with this work lies in the model operationalizing it through the ergonomic design of the workstation and the operator's participation, an articulation not reported in that literature. Relative to these approaches and Human-Centric SMED, the contribution is their integration within a frugal digital-transformation framework for this extrusion case. Transfer requires a local baseline assessment, time study, process/model calibration and local validation.

VII. Conclusions

The integration of SMED 4.0 with a Human Centricity approach and predictive maintenance based on historical data raises the projected operational availability of the HDPE extrusion line from 81.46 % to 88.51 %, with a 50.53 % reduction in changeover time and a 25.59 % reduction in mechanical failures. The economic evaluation indicates viability, with an NPV of S/ 141 688 and a payback of 1.58 years. Overall, the contribution constitutes a frugal, potentially transferable digital transformation route in continuous processes of the plastics sector, which brings operational performance closer to the world-class benchmark without large investments in sensing infrastructure.

Discrete-event simulation validation proved adequate for Component 1 and computational-prototype validation for Component 2, by making it possible to evaluate the performance of the predictive system over historical data before its deployment in the plant. On the non-economic side, the proposal drives the digital maturity of line L3 toward the Transparency stage with progress toward Predictive Capability.

The main limitation lies in the scope of Component 2, which excludes the Electrical and Control System due to the low frequency of events per sub-cause. Future work contemplates the incorporation of embedded sensors to move toward condition-based maintenance, the integration with ERP/MES systems and the extension of the scheme to the other production lines through transfer learning.

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