Improving Incubator Manufacturing Performance Through RPW-Based Line Balancing and Constraint Management

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ABSTRACT

In the regulated field of medical device manufacturing, optimizing production efficiency without compromising compliance is critical, particularly for small and medium-sized enterprises (SMEs) operating in resource-constrained environments. This study addresses production inefficiencies in the assembly of the TSN 89 TR neonatal incubator at PT Tesena Inovindo, an Indonesian manufacturer, by implementing an integrated improvement framework. The approach combines Lean Manufacturing for process stabilization, the Ranked Positional Weight (RPW) method for line balancing, and the Theory of Constraints (TOC) for bottleneck resolution. Time study data were collected across 30 cycles per task to ensure reliable estimates of average cycle times, based on the Central Limit Theorem. The initial production system exhibited unbalanced workloads, high idle time, and frequent work-in-process (WIP) accumulation. After reconfiguration, the number of workstations was reduced from ten to eight, the cycle time decreased by 23.8%, and daily output increased from four to six units. Line efficiency improved from 67.2% to 89.5%, with idle time dropping from 32.8% to 10.5%. These gains were achieved without automation or additional labor, relying solely on empirical task analysis and workflow redesign. The study offers a replicable, low-cost framework for optimizing semi-manual assembly lines in regulatory environments. It demonstrates that substantial performance improvements can be achieved through structured, data-driven interventions, making it particularly valuable for SMEs in emerging markets seeking ISO 13485 compliance and operational excellence.

DOI: https://doi.org/10.24002/ijieem.v8i1.11454

Keywords: Lean Manufacturing, Line Balancing, RPW Method, Medical Device Production, Time Study, Theory of Constraints

Research Type: Research Paper

Article History: Received June 10, 2025; Revised March 16, 2026; Accepted May 8, 2026

How to cite: Sumasto, F., Imansuri, F., Pratama, I.R., Arohman, A.W., & Purbaningrum, S.P. (2026). Improving incubator manufacturing performance through RPW-based line balancing and constraint Management. *International Journal of Industrial Engineering and Engineering Management, 8*(1), 1-11.

1. INTRODUCTION

Medical device manufacturing plays a critical role in advancing global healthcare, particularly in neonatal care, where equipment such as infant incubators supports the survival of premature and low-birth-weight infants. In neonatal intensive care units (NICUs), incubators provide a controlled environment essential for thermoregulation, making them a core component of life-saving interventions (Constanza, 2021). As healthcare systems strive to reduce neonatal mortality, the global demand for reliable, cost-effective incubator production continues to grow, especially in low- and middle-income countries.

In this highly regulated industry, manufacturers must simultaneously ensure efficiency and compliance with international standards such as ISO 13485 and FDA 21 CFR Part 820. These standards require robust documentation, traceability, and consistent quality throughout production. Meeting such demands poses a particular challenge for small to medium-sized enterprises (SMEs) in emerging economies, where manual operations and resource limitations are common (Huang et al., 2022; Klimecka-Tatar & Ingaldi, 2022).

Indonesia is actively promoting medical technology independence through policies that encourage domestic production. PT Tesena Inovindo (TSNI), a mid-sized Indonesian manufacturer, produces the TSN 89 TR neonatal incubator to meet growing national demand. However, TSNI has faced significant operational inefficiencies in its semi-manual production line. These include unbalanced task distribution, excessive idle time, and the accumulation of work-in-process (WIP), leading to reduced throughput and increased per-unit costs.

Preliminary observations indicated that traditional Lean tools had been applied inconsistently, without a structured improvement framework. However, there remains a clear gap in the existing literature regarding the integrated application of Lean Manufacturing, the Ranked Positional Weight (RPW) method, and the Theory of Constraints (TOC) within resource-constrained, regulated manufacturing environments such as medical device assembly in emerging markets. While RPW and TOC have each been applied individually across various industrial contexts, few empirical studies have rigorously examined their combined implementation in low-automation settings subject to strict compliance standards such as ISO 13485.

Additionally, much of the existing literature focuses on high-volume or automated production systems, limiting generalizability to small and medium-sized enterprises (SMEs) with semi-manual operations (Narke & Jayadeva, 2020; Sumasto et al., 2023). This study seeks to address that research gap by offering a structured, data-driven improvement model for such constrained environments, bridging theoretical principles with practical implementation. Furthermore, considerable variation in task times caused material bottlenecks and disrupted flow across workstations. This highlighted the need for a comprehensive approach that not only balances task loads but also addresses systemic production constraints.

To address these challenges, this study adopts an integrated methodology that combines three established frameworks: (1) Lean Manufacturing, to reduce non-value-added activities and standardize workflows; (2) the Ranked Positional Weight (RPW) method, to achieve balanced task allocation across workstations; and (3) the Theory of Constraints (TOC), to systematically identify and resolve production bottlenecks. A structured time study with a minimum of 30 observations per task was conducted to ensure representative cycle time measurements, grounded in the principles of the Central Limit Theorem (CLT) (Imansuri et al., 2024; Özcan, 2018; Pulansari & Nugraha, 2023). While no inferential statistical tests were performed, the CLT informed the sampling design, ensuring data reliability.

Although RPW, TOC, and Lean have each been studied extensively, few works have explored their combined application in regulated, small-batch medical device manufacturing environments. This study aims to close that gap by proposing a practical, data-driven framework tailored to the constraints and regulatory demands of SMEs like TSNI. The results offer both methodological and contextual contributions to operational optimization in healthcare manufacturing systems.

This study addresses a critical gap in the literature by proposing the first integrated framework combining Lean Manufacturing, RPW-based line balancing, and TOC for semi-manual medical device assembly lines in resource-constrained SMEs. Unlike prior works that focus on individual methodologies, this research demonstrates how synergistic integration of these tools can achieve ISO 13485-compliant efficiency gains without capital investment, a novel contribution to both operational and regulatory contexts in emerging markets.

2. LITERATURE REVIEW

2.1. Medical Device Production Systems

Medical device production differs significantly from consumer goods manufacturing due to regulatory oversight, product complexity, and patient safety considerations. Systems must be designed to ensure both traceability and consistency. This is especially important for neonatal devices, where environmental regulation is tightly coupled with patient outcomes (Swain et al., 2015).

The structure of production systems in this field often combines automated and manual tasks, each requiring synchronization. In developing countries, a high reliance on manual assembly persists due to cost constraints. This increases variability and makes the system vulnerable to inefficiencies if not well-balanced (Mazzocato et al., 2012).

Several researchers have emphasized that system design in medical device manufacturing should integrate quality assurance and throughput optimization concurrently. Ignoring one dimension often undermines the other, especially when feedback loops between stages are weak or missing (Mourtzis et al., 2016).

2.2. Lean Manufacturing in Regulated Environments

Lean Manufacturing aims to eliminate waste and streamline processes. It has proven effective in healthcare manufacturing, particularly in areas involving repetitive and standardized tasks. Lean tools such as 5S, Kaizen, and Value Stream Mapping are widely adopted across regulated industries (Womack & Jones, 1997).

In medical device environments, however, lean tools must be adapted to meet regulatory frameworks. Documentation, validation, and traceability cannot be sacrificed for speed. Researchers have noted that Lean implementation must align with documentation protocols required under ISO 13485 and FDA 21 CFR Part 820 (Hasle et al., 2012).

Recent studies show that Lean, when combined with visual controls and operator engagement, improves compliance, productivity, and morale simultaneously. Visual SOPs and standardized work instructions contribute significantly to reducing errors and downtime (Duraisamy et al., 2023; Salim et al., 2021).

While Lean principles have been applied in regulated environments (Hasle et al., 2012) prior studies seldom address line balancing challenges in low-automation settings. For instance, (Sallam, 2024) achieved waste reduction in pharmaceutical manufacturing using Lean, but omitted workload balancing. Similarly, Applied TOC to resolve bottlenecks in high-volume electronics assembly, but did not incorporate precedence-based task allocation. This study bridges these gaps by unifying Lean, RPW, and TOC into a cohesive framework tailored for SMEs, where regulatory compliance and manual task variability coexist.

2.3. Ranked Positional Weight (RPW) Method in Assembly Systems

The RPW method, developed by Helgeson and Birnie (1961) remains a widely used heuristic for solving line balancing problems (Lorou et al., 2021). It assigns weights to tasks based on the sum of their operation times and all successor tasks, guiding assignment decisions across stations.

In semi-automated lines, especially where operations are human-driven, RPW helps maintain balance by ensuring precedence and cycle time constraints are respected. RPW is particularly suited to systems that have low automation, moderate task variability, and medium-volume outputs (Nearchou, 2011).

Recent works by Delice et al. (2023) and Özcan (2018) validate RPW's efficacy in automotive assembly, yet its application in medical device production remains unexplored. By adapting RPW to a regulated, small-batch environment, this research extends its utility beyond traditional sectors and provides actionable insights for similar SMEs.

2.4. Theory of Constraints (TOC) in Healthcare Manufacturing

TOC, proposed by Goldratt (Goldratt & Cox, 1984), identifies the "weakest link" or bottleneck in a system and optimizes it using five structured steps. These steps help maintain throughput without introducing excess capacity in non-bottleneck stations (Mabin & Balderstone, 2003).

In healthcare-related manufacturing, TOC can be applied not only to physical bottlenecks like machine time or skilled labor, but also to systemic issues such as long setup times or interdepartmental misalignments. Researchers argue that TOC promotes global optimization over local efficiency, which is especially valuable in systems constrained by regulation and capacity.

Recent case studies in pharmaceutical and medical supply chains show that TOC implementation improves throughput, reduces WIP, and enables more predictable lead times. These benefits align well with the objectives of Lean and RPW in regulated environments (Imansuri et al., 2024; Rajendran & Alicke, 2007).

2.5. Central Limit Theorem (CLT) in Time Study Validation

Statistical validation is critical in regulated industries. The Central Limit Theorem (CLT) ensures that, given a large enough sample size, the sampling distribution of the mean will be approximately normal. This allows for the use of confidence intervals, hypothesis testing, and control charts (Montgomery et al., 2010).

In time studies, CLT supports the validation of average cycle times and helps in determining whether observed improvements are statistically significant. This is particularly important in quality-driven environments where random variation must be separated from actual improvements (Niebel & Freivalds, 2003).

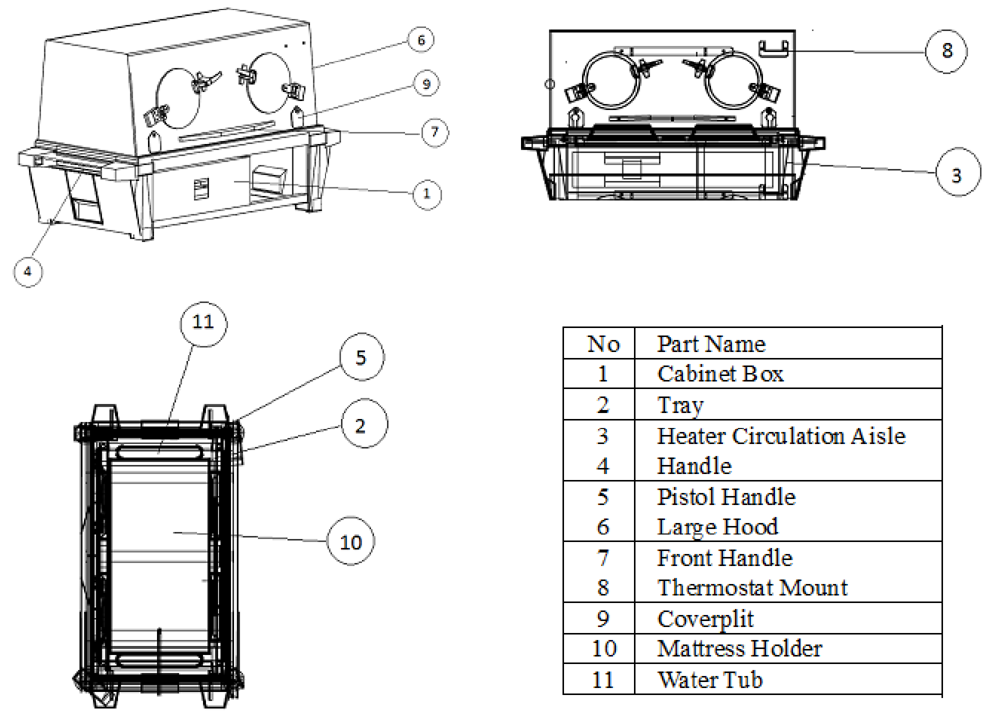
CLT has become a cornerstone of Six Sigma and Lean Six Sigma projects, where it underpins the "Measure" and "Analyze" phases of the DMAIC framework (Sumasto et al., 2023). In this study, it ensures that interventions based on RPW and TOC are not only operationally sound but also statistically reliable.

2.6. Integrated Application: Lean, TOC, and CLT

The integration of Lean, TOC, and CLT offers a powerful framework for manufacturing optimization. Lean reduces waste, TOC addresses the limiting factor, and CLT validates the outcome. Several case studies support this triadic approach. For instance, Umble and Srikanth (1990) reported that combining TOC with statistical quality control in a small device manufacturing facility led to a 27% increase in throughput and a 33% reduction in WIP. The integration is especially suitable for small-batch, high-reliability production, such as neonatal incubators, where both compliance and efficiency are paramount. As per Rahani and Al-Ashraf (2012) such hybrid frameworks are the future of flexible manufacturing.

2.7. Technical Considerations in SMEs and Method Integration Justification

Small and medium-sized enterprises (SMEs), particularly in regulated industries like medical device



No	Part Name
1	Cabinet Box
2	Tray
3	Heater Circulation Aisle
4	Handle
5	Pistol Handle
6	Large Hood
7	Front Handle
8	Thermostat Mount
9	Coverplit
10	Mattress Holder
11	Water Tub

Figure 1. Technical Drawing of TSN 89 TR

manufacturing, face unique operational constraints such as limited automation, capital limitations, and high variability in manual operations (Huang et al., 2022; Klimecka-Tatar & Ingaldi, 2022). These characteristics necessitate integrated approaches that address both systemic and task-level inefficiencies. While Lean Manufacturing focuses on eliminating waste and stabilizing the work environment, its effectiveness in SMEs is often undermined by inconsistent implementation due to informal processes and workforce variability (Narke & Jayadeva, 2020).

The RPW method offers structured task allocation under precedence constraints, ideal for semi-manual systems, but lacks mechanisms to adapt dynamically to bottleneck shifts. The Theory of Constraints (TOC), meanwhile, provides a systemic lens to manage throughput by addressing the most critical bottlenecks iteratively (Goldratt & Cox, 1984). The integration of these three methods responds directly to the operational reality in SMEs, where isolated interventions often fail to produce sustainable outcomes. Therefore, this study proposes a hybrid Lean-RPW-TOC framework that leverages the strengths of each method to produce cumulative and coherent improvements.

2.8. Lean and TOC implementation in Southeast Asian SMEs

Prior studies in Southeast Asia have highlighted both the promise and practical challenges of applying Lean Manufacturing and TOC in SME contexts. In Thailand, productivity improvement was achieved through the integration of Lean, JIT, and production technology, especially in resource-limited settings (Burawat, 2024). Malaysian SMEs have shown active adoption of Lean-TQM-TOC frameworks under quality certifications like ISO 9001 and ISO 14001 (Norhafizan, 2015; Zadry & Yusof, 2006), reinforcing the feasibility of hybrid models. Moreover, implementation studies in Indonesia's traditional SMEs, such as batik manufacturing, demonstrated how customized scheduling based on TOC principles effectively reduced makespan (Arohman et al., 2019).

3. METHODOLOGY

3.1. Research Design and Case Background

This research adopts a quantitative case study approach aimed at improving the production performance of the TSN 89 TR (Figure 1) neonatal incubator at PT Tesena Inovindo (TSNI), a medium-scale medical device manufacturer in Indonesia. The case was selected due to evident inefficiencies in the assembly line, including cycle time variation, unbalanced task distribution, and excessive work-in-process (WIP) issues commonly found in small-batch, semi-manual operations under regulatory constraints.

The production line consists of sequential workstations that include mechanical assembly, electrical wiring, functional testing, and final packaging. Most tasks are performed manually, leading to time variability and imbalance across stations. The initial layout lacked formal line balancing, contributing to bottlenecks and workflow disruptions. By focusing on a single product line with stable demand, the study ensured consistent task characteristics and minimized variability unrelated to the intervention.

3.2. Data collection and time study procedure

Primary data were gathered through direct observation and manual time measurement using a calibrated digital stopwatch. For each production task, 30 observations were recorded, an approach aligned with the Central Limit Theorem (CLT), which allows the sampling distribution of the mean to approximate normality when the sample size is sufficiently large. While no hypothesis testing was conducted, this sampling strategy ensured reliable estimates of average task durations, which were used for line balancing. The observed data were processed to remove any significant outliers, verified through visual inspection and consistency checks. Task sequences were structured using a precedence diagram constructed in collaboration with production supervisors to reflect actual operational workflows. These task time averages formed the basis for subsequent Ranked Positional Weight (RPW) analysis (Table 1). A precedence diagram was developed collaboratively with production supervisors to visualize task dependencies and operational sequencing. This diagram ensured that all successor and predecessor constraints were respected during the RPW analysis, and it served as a foundation for accurately assigning tasks to workstations through semi-manual operations under regulatory constraints.

Table 1. Average Completion Time per Operation (Time Study)

Workstation	Task	Average Time (Sec)
1	Cut Plate	210
2	Frame Welding	360
3	Painting	300
4	Frame Assembly	180
5	Cable Installation	450
6	Module Installation	240
7	Calibration	390
8	Final Check	300
9	Cleaning	120
10	Packaging	150

To ensure clarity and reproducibility of the balancing logic, each task was assigned a Ranked Positional Weight, calculated as the sum of its own operation time and that of all its downstream (successor) tasks. Tasks were then sorted in descending order of weight and grouped into workstations such that the total task time at each station did not exceed the target cycle time.

Line efficiency (LE) was calculated using the formula:

$$LE = \left(\frac{\Sigma ST}{CT\ x\ K}\right) x100\% \quad (1)$$

Where ΣST is the total standard time across all tasks, CT is the target cycle time, and K is the number of workstations. Balance Delay (BD), which quantifies idle time inefficiencies, was computed as:

$$BD = \left(\frac{(CT\ x\ K) - \Sigma ST}{CT\ x\ K}\right) x100\% \quad (2)$$

These metrics were used to evaluate both the initial and improved configurations. All calculations were validated using spreadsheet-based modeling to confirm the feasibility and integrity of task assignments.

3.3. Lean manufacturing implementation

The implementation of Lean tools was not limited to generic 5S routines. Specific applications included red-tag campaigns to eliminate obsolete tools, shadow boards for standardized tool placement, and visual SOPs to guide operator tasks consistently. These initiatives formed the foundation for stabilizing process variation, which is a prerequisite for reliable line balancing.

Prior to line balancing, Lean Manufacturing principles were applied to stabilize the production environment and reduce process variability. Several tools were systematically implemented to prepare the shop floor for subsequent workflow reconfiguration. A structured 5S program was launched, including red-tagging campaigns, a standardized layout for tool and material placement, and visual markings to designate storage zones. These efforts reduced non-value-adding motion and improved part accessibility.

Additionally, visual Standard Operating Procedures (SOPs) were deployed at each station to minimize interpretation errors. These SOPs featured step-by-step photos and cycle time targets, ensuring process uniformity and reducing variability across shifts. Visual control boards were introduced to track takt time adherence and daily output, offering real-time feedback to operators. These boards helped reinforce accountability and made deviations immediately visible to the production team.

Operator involvement was emphasized throughout the Lean implementation. Workers participated in workstation layout redesigns and provided feedback during daily briefings. This approach supported cultural change and enhanced ownership of improvement initiatives. Together, these Lean tools laid a stable foundation for conducting accurate time studies and executing reliable RPW-based line balancing.

3.4. Line balancing using RPW

Following environmental stabilization, the production line was redesigned using the RPW method, a heuristic technique for line balancing under precedence constraints. Each task was assigned a ranked positional weight by summing its own operation time and the times of all successor tasks. Tasks were then ordered from highest to lowest RPW and assigned to workstations based on a target cycle time, ensuring that each station remained within time limits while adhering to task precedence (Table 2).

The original system utilized ten workstations, which displayed significant inefficiencies and idle time. After RPW-based reconfiguration, the layout was reduced to eight balanced stations, each designed to meet the production takt time of 91.8 minutes. Assignments were validated using manual cross-checking and simulation in spreadsheet models to ensure workload feasibility and balance.

The RPW method was selected due to its compatibility with precedence-constrained environments typical in medical device assembly. Task assignments were cross-validated with production supervisors using actual Gantt-like flow maps. The RPW assignments respected strict compliance workflows under ISO 13485, ensuring traceability. A precedence matrix was developed (Figure 2), illustrating the flow logic and dependencies among tasks, which informed the allocation matrix presented in Table 2.

Table 2. Ranked Positional Weight (RPW) for Each Task

Task	Cycle Time (Sec)	Ranked Positional Weight (RPW)
Cut Plate	210	2700
Frame Welding	360	2490
Painting	300	2130
Frame Assembly	180	1950
Cable Installation	450	1770
Module Installation	240	1320
Calibration	390	1080
Final Check	300	690
Cleaning	120	390
Packaging	150	150

3.5. Constraint identification and process improvement

The Theory of Constraints (TOC) was applied after balancing to identify and mitigate system bottlenecks. Initially, the electrical wiring station emerged as the primary constraint. Interventions included offloading pre-assembly steps, improving ergonomics, and implementing customized jigs to reduce handling time. Once resolved, a secondary constraint was observed at the functional testing stage, which was addressed by introducing visual guides and digital calibration tools to standardize testing procedures. Following the line balancing phase, the Theory of Constraints (TOC) methodology was employed to address residual inefficiencies in the production system. The intervention followed TOC's Five Focusing Steps: identifying the primary constraint, exploiting existing capacity, subordinating supporting processes, elevating the constraint, and iterating as necessary. Each production station was reviewed through direct observation and operator interviews to determine bottlenecks in task duration, resource dependency, or process variability. This approach enabled systematic diagnosis of flow-disrupting issues and guided targeted interventions aligned with takt time requirements.

4. RESULTS AND DISCUSSIONS

4.1. Result

The production performance of the TSN 89 TR incubator line at PT Tesena Inovindo showed considerable improvement after the application of Lean Manufacturing, RPW-based line balancing, and TOC principles. Prior to intervention, the production process was characterized by high variability in task times and uneven workload distribution across workstations. These inefficiencies resulted in long cycle times and limited daily throughput. Data collection was conducted over 30 cycles per operation, providing a reliable estimate of the average task duration for each production step.

The initial average cycle time per unit was recorded at 120.6 minutes, a figure that limited the production line to four incubators per day. The production layout featured ten workstations, many of which exhibited underutilization or frequent idle time. Task assignment lacked a systematic approach, and precedence constraints were not formally accounted for. This setting provided a clear opportunity for reconfiguration based on time study data and operational logic. After implementing RPW-based line balancing, the total number of workstations was reduced to eight, while keeping each station's

Task	Cut Plate	Frame Welding	Painting	Frame Assembly	Cable Installation	Module Installation	Calibration	Final Check	Cleaning	Packaging
Cut Plate		1	1	0	0	0	0	0	0	0
Frame Welding	-1		1	1	0	0	0	0	0	0
Painting	-1	1		1	0	0	0	0	0	0
Frame Assembly	0	-1	1		1	0	0	0	0	0
Cable Installation	0	0	0	-1		1	0	0	0	0
Module Installation	0	0	0	0	-1		1	0	0	0
Calibration	0	0	0	0	0	-1		1	1	0
Final Check	0	0	0	0	0	0	-1		1	1
Cleaning	0	0	0	0	0	0	-1	1		1
Packaging	0	0	0	0	0	0	0	-1	-1	

Figure 2. Precedence Matrix of TSN 89 TR

workload under the defined takt time (Table 3). Task allocation was restructured based on ranked positional weights, ensuring that high-priority operations with multiple dependencies were scheduled early. The revised configuration optimized both sequence flow and labor allocation. As a result, the average cycle time per unit decreased significantly to 91.8 minutes (Table 4).

Table 3. Task Allocation After RPW-Based Line Balancing

Workstation	Task	Total Cycle Time (Sec)
1	Cut Plate	210
2	Frame Welding	360
3	Painting	300
4	Frame Assembly	180
5	Cable Installation	450
6	Module Installation	240
7	Calibration + Final Check	690
8	Cleaning + Packaging	270

Table 4. Comparison of Production Efficiency Before and After Implementation

Parameter	Before	After
Number of Workstations	10	8
Cycle Time (minutes)	120.6	91.8
Daily Output (units)	4	6
Line Efficiency (%)	67.2	89.5
Idle Time (%)	32.8	10.5

This cycle time reduction represents an improvement of 23.8%, accomplished without automation or additional labor input. The gains were purely the result of workflow redesign, workload equalization, and station-specific efficiency enhancements. The output increased from four to six units per shift, a 50% boost in daily production within the same operational hours. These results underline the power of low-cost, data-driven interventions in production optimization.

Line efficiency was another key performance indicator analyzed during the study. In the pre-intervention phase, the production line achieved only 67.2% efficiency, meaning nearly one-third of available time was not utilized for productive work. Post-intervention, this figure rose to 89.5%, indicating a much more balanced and synchronized workflow across stations. This 22.3-point increase highlights the improved alignment between station time and takt time.

Concurrently, idle time across the line dropped from 32.8% to just 10.5%. Such reductions in idle time are critical in regulatory environments, where timing, sequencing, and compliance must work in harmony. Minimizing non-value-adding delays enhances traceability and process reliability, both of which are required under ISO 13485 standards. These improvements further contribute to increased predictability in lead times and production scheduling.

The primary bottleneck prior to intervention was identified at the electrical wiring station (Table 5). This station exhibited consistently longer task times and often accumulated work-in-process (WIP) materials. To address this, several corrective actions were implemented: preparatory work was redistributed, ergonomic fixtures were introduced, and task-specific jigs were deployed. These changes reduced handling time and streamlined wire management, improving overall flow.

While the RPW-based line balancing method effectively redistributed tasks based on precedence and task weights, it did not fully resolve performance fluctuations caused by resource variability and operational inconsistencies. The application of TOC after balancing proved essential for detecting and mitigating real-time constraints. For example, the Cable Installation process exhibited prolonged durations due to suboptimal ergonomics and manual handling, while the Calibration and Final Check stages suffered from procedural inconsistency and transitional delays. Through iterative application of TOC's Five Focusing Steps, customized solutions such as ergonomic jigs, standardized digital SOPs, and visual guides were introduced (Table 5). These interventions not only addressed individual bottlenecks but also ensured overall system flow stability under manual labor conditions, reinforcing the integrative strength of the Lean-RPW-TOC framework. Table 6 summarizes the practical implementation of the TOC's Five Focusing Steps in the case study, highlighting the targeted actions taken to address system constraints.

Once the electrical station was optimized, the functional testing station emerged as the next critical constraint. Test procedures were time-consuming and inconsistent, which disrupted the downstream flow. Standardized testing protocols were introduced alongside visual aids and digital calibration tools to improve task execution. These enhancements resulted in faster, more repeatable testing with less reliance on operator judgment. Through this iterative approach, aligned with the Five Focusing Steps of TOC, the production system reached a state of equilibrium. No station exceeded the target cycle time, and workflow congestion was significantly reduced. Material handling was smoother, and operator transitions between tasks became more efficient. The system achieved consistent takt alignment and stability throughout the shift. The performance gains observed in this study validate the effectiveness of integrated Lean-RPW-TOC frameworks for low-volume, semi-manual production systems. The production improvements were realized without capital expenditure or automation

Table 5. Bottleneck Identification and TOC-Based Solutions

Production Stage	Problem	TOC Solutions
Cable Installation	Processing time is too long	Task redistribution & ergonomic jigs
Calibration	Inconsistent procedures	SOP standardization & digital calibration
Final Check	Transition between stations is slow	Visual guides & digital checklists

Table 6. TOC's Five Focusing Steps – Application in Case Study

TOC Step	Description	Application in Study
Identify	Locate the most critical constraint (bottleneck) in the process.	Cable Installation was found to have the longest processing time and high WIP accumulation.
Exploit	Maximize the utilization of the constraint without major changes or investments.	Pre-assembly steps were streamlined, and non-value activities were removed at the Cable Installation stage.
Subordinate	Align all other processes to support the constraint's performance.	Workstation sequencing and takt time adjustments were synchronized to prevent upstream overload.
Elevate	Take additional steps (e.g., tools, redesign) to remove the constraint.	Ergonomic jigs, digital calibration tools, and visual SOPs were introduced to reduce handling time.
Repeat	Reassess the system to identify the next constraint and restart the cycle.	Once Cable Installation was resolved, Calibration and Final Check became the new focus of improvement.

upgrades. These findings affirm that small and medium-sized manufacturers can benefit from structured process redesign driven by empirical data. The interventions delivered meaningful operational results aligned with regulatory standards.

4.2. Discussion

The improvements in productivity and efficiency observed in this study are highly relevant to manufacturers operating in constrained environments. Many SMEs in developing countries, especially in medical device manufacturing, lack the resources for automation or digital transformation. Yet, they are required to meet stringent quality and compliance standards. This study demonstrates that practical, human-centered improvements can still deliver measurable gains under such conditions.

The use of time study techniques and the application of CLT as a sampling guide provided a reliable foundation for estimating average task durations. While no inferential statistics were applied, the design ensured that the data collected were sufficient to represent typical performance. By focusing on descriptive performance indicators such as cycle time, throughput, and line efficiency, the study remained operationally grounded. This approach enhances the utility of the results for practitioners and production engineers. While the productivity gains and improved efficiency are noteworthy, several limitations must be acknowledged. First, the study was conducted within a single production environment focused on a specific product (TSN 89 TR incubator). As such, generalizability to other production types, especially high-mix or high-automation systems, may be limited. Additionally, although the time study methodology adhered to the Central Limit Theorem, no inferential statistics or confidence intervals were computed to validate the significance of observed improvements.

Compared to previous research, this study aligns with findings from Matondang et al. (2010), who demonstrated the effectiveness of heuristic methods like RPW in medium-volume, semi-manual systems. However, unlike most RPW studies that do not address regulatory constraints, our study integrates quality assurance concerns tied to ISO 13485, highlighting a critical contextual adaptation rarely explored in the literature. Furthermore, the synergy of Lean, TOC, and RPW offers a multidimensional improvement model not commonly applied in regulated, resource-limited environments, thereby extending the work of Mabin and Balderstone (2003) and Umble & Srikanth (1990).

Future studies should explore the integration of digital time-tracking tools and simulation software to validate heuristic task assignments against optimization-based approaches such as genetic algorithms or integer programming. Investigating the impact of operator skill variability and learning curves over time could also provide deeper insights into system dynamics under semi-manual conditions.

The findings reinforce the feasibility of low-cost, data-driven redesign in regulated production environments, yet underscore the need for broader replication studies and more rigorous statistical evaluation. The RPW method proved particularly effective in this case due to its compatibility with semi-manual systems. Unlike optimization algorithms that may require advanced software or modeling capabilities, RPW is a heuristic method that can be implemented with minimal tools. The precedence diagram, used in conjunction with ranked task weights, enabled a more logical and balanced assignment of work. It also encouraged managerial participation in the improvement process.

The integration of Lean tools, such as 5S and visual SOPs, helped standardize the workplace environment before balancing was attempted. This stabilization was critical in reducing variability and ensuring the reliability of the time study data. Operator engagement and daily feedback loops fostered a culture of continuous improvement. These soft-skill dimensions complemented the technical interventions and contributed to the sustainability of the changes.

TOC played a strategic role in maintaining flow after balancing was achieved. Identifying and relieving system constraints ensured that production gains were not temporary. The iterative nature of the TOC methodology, identify, exploit, subordinate, elevate, and repeat, was essential in driving further refinement. This focus on global optimization rather than localized efficiency helped sustain overall system performance. A major takeaway from this study is that productivity improvements do not necessarily require investment in automation. Instead, structured observation, analytical task breakdown, and participatory redesign can yield comparable benefits. For regulatory-bound SMEs, such improvements can enhance audit-readiness and compliance, while simultaneously reducing operational cost per unit. These advantages position the organization for long-term competitiveness.

In addition to production benefits, the study has implications for workforce development. By involving operators in task reorganization and layout improvements, the project fostered greater process ownership and problem-solving capacity. This engagement not only supports Lean implementation but also aligns with ISO 13485's emphasis on competency and training. Human capital thus becomes a key enabler in sustaining process excellence.

The synergy between Lean, RPW, and TOC became evident through the sequence of interventions. Lean principles enabled environmental control and task standardization, RPW rationalized workload distribution, and TOC addressed residual systemic bottlenecks that could not be resolved through static task balancing alone. For instance, although Cable Installation and Calibration appeared as time-intensive tasks from the outset, only through TOC were ergonomic and procedural inefficiencies resolved sustainably.

This tri-layered integration demonstrates that in SMEs, addressing both micro-level task flow (via RPW) and macro-level system flow (via TOC) ensures a more resilient and balanced production system. Additionally, operator involvement throughout Lean and TOC activities not only improved process ownership but also aligned well with ISO 13485's human competency standards. Therefore, the integrated framework is not merely sequential but interactive; each method reinforces the other in enabling sustainable improvements.

While the study achieved its objectives, several limitations should be acknowledged. The improvements were observed in a single production line with a stable product configuration. Future studies could explore how these methods perform under higher product mix variability or in multi-line environments. Additionally, while CLT was used to inform sampling size, incorporating inferential methods in future work could add analytical rigor.

Nevertheless, the operational gains reported here demonstrate that data-informed line design can transform performance in resource-limited contexts. The methods are replicable and scalable, particularly for manufacturers of regulated products that must balance cost, compliance, and capacity. The hybrid use of RPW, Lean, and TOC constitutes a flexible and robust improvement strategy. Its application in this case provides a valuable reference for similar organizations.

In conclusion, this study contributes both empirical insights and methodological guidance for optimizing assembly lines in regulated, low-volume medical device manufacturing. It reinforces the idea that simplicity, structure, and systematic thinking can yield results comparable to high-tech interventions. The findings advocate for empowering local manufacturers through knowledge-driven process engineering. This model can serve as a stepping stone toward broader operational maturity and sustainable industry development.

The results are consistent with similar Lean-TOC adaptations observed in Southeast Asian SMEs, where high labor variability and low automation levels require pragmatic tools, strong visual systems, and simplified scheduling (Burawat, 2024; Mustapha et al., 2019). While this study adds to the limited literature on regulated manufacturing environments in the region, further alignment with Malaysian and Thai case studies underscores the generalizability of process-driven frameworks.

4.3. Limitations and future research

While this study demonstrates the effectiveness of integrating Lean, RPW, and TOC in a regulated SME manufacturing context, several limitations must be acknowledged:

1) Single-Case Scope: The study focuses exclusively on one production line (TSN 89 TR neonatal incubator) within a single company. Results may not be directly transferable to high-mix, high-volume, or automated production systems.
2) No Inferential Statistical Analysis: Although the Central Limit Theorem was applied for time study sampling, no hypothesis testing or confidence intervals were computed. This limits the statistical generalizability of observed improvements.
3) Manual Time Measurement: Time data were collected via manual stopwatch methods, which, despite calibration, are subject to observer bias and variation.
4) Limited Digital Integration: The intervention relied on heuristic methods and manual visualization tools. Digital line balancing software, discrete-event simulation, or automated data logging could have improved accuracy and scalability.

Future research could explore:

1) Applying this hybrid framework to multi-product assembly lines or multi-plant environments.
2) Incorporating optimization-based balancing methods (e.g., genetic algorithms) for comparison with RPW.
3) Evaluating the long-term sustainability of Lean and TOC interventions under workforce turnover and demand shifts.
4) Investigating the impact of operator learning curves and ergonomic redesign on line performance in greater depth.

5. CONCLUSIONS

This study presents a structured, integrated approach to improving production performance in a semi-manual, small-batch medical device manufacturing environment. By combining Lean Manufacturing, Ranked Positional Weight (RPW) line balancing, and the Theory of Constraints (TOC), the research offers a practical framework tailored for resource-constrained operations that must still meet rigorous regulatory standards.

The application of RPW-based balancing reduced the number of workstations from ten to eight and decreased the average cycle time by 23.8%, resulting in a 50% increase in daily output. In parallel, Lean-driven improvements such as 5S, visual SOPs, and standardized workflows helped stabilize production, while TOC methods enabled iterative identification and resolution of process bottlenecks. These interventions collectively raised line efficiency from 67.2% to 89.5% and significantly minimized idle time.

Importantly, the improvements were achieved without any automation or capital investment, relying entirely on empirical time studies, task reallocation, and operator engagement. This affirms the feasibility and replicability of the proposed framework in similar industrial settings, particularly among small to medium-sized enterprises (SMEs) operating in emerging economies. Although the study focused on a single production line with a stable product configuration, its findings suggest that meaningful performance gains can be realized through disciplined, data-driven process redesign. Future research may build on this model by applying inferential analysis, extending to more diverse product lines, or integrating digital tools to further enhance system responsiveness. Ultimately, this work demonstrates that even in constrained manufacturing environments, operational excellence is achievable through systematic planning, continuous improvement, and strategic alignment between people, processes, and production flow.

ACKNOWLEDGEMENT

The authors would like to express their sincere gratitude to PT Tesena Inovindo. for their invaluable support and cooperation in facilitating the case study implementation. Their assistance in providing access to data, resources, and insights has greatly contributed to the depth and quality of this research. This collaboration has been instrumental in advancing our understanding and analysis, and we deeply appreciate their commitment to academic and industrial development.

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