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Enhancing Production Efficiency and Waste Reduction in Medical Tube Extrusion through Self-Centering Die Design and Material Optimization

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Abstract

Precision and efficiency in the manufacturing of medical-grade tubing are critical factors that directly influence both production costs and product safety. This research addresses the persistent challenges of high material waste and prolonged setup times in a medical tube extrusion process. The study identifies that the traditional die centering mechanism, which relies heavily on operator skill and visual judgment for alignment, is the primary cause of significant wall thickness inconsistency and frequent machine downtime. To mitigate these issues, a systematic improvement was implemented through the Plan-Do-Check-Act (PDCA) cycle, integrating Lean manufacturing principles with advanced engineering design. Key interventions included the transition to SUS420J2 stainless steel for die components to minimize surface oxidation and the development of a specialized Center Die Gauge to standardize measurements. The culmination of this study was the engineering of a self-centering die (Die Model 2), which eliminates the need for manual bolt adjustments. Experimental results demonstrate a substantial improvement in operational performance: the setup procedure was streamlined from 23 to 15 steps, and the average setup duration was reduced by 9.33 minutes per lot. Furthermore, total plastic waste decreased by 7.88 kg per lot. Quality analysis showed that wall thickness deviation was minimized from 4.13% to 2.08%, surpassing the industrial standard requirement. These enhancements collectively resulted in a productivity increase of 3.1% and a monthly cost reduction of 11,300.65 THB, proving the effectiveness of the proposed design in high-precision manufacturing environments.

Keywords
Medical Tube Extrusion, Die Design Optimization, Waste Reduction, Self-centering Die, Setup Time Improvement.

1. Introduction
The medical device industry is characterized by its stringent quality standards and regulatory requirements, particularly for components that interact directly with patients, such as medical-grade tubing. Within this sector, the polymer extrusion process plays a pivotal role, requiring extreme precision in maintaining wall thickness and concentricity. Any minor deviation from specified tolerances leads to non-conforming products, which not only poses a risk to patient safety but also significantly increases production costs due to material wastage and unplanned machine

downtime. As global market competition intensifies, manufacturers are compelled to transition toward lean operations to minimize operational waste and optimize changeover processes while adhering to rigorous safety regulations.

In high-precision manufacturing, the stability of the extrusion process is often undermined by traditional setup methods. This research focuses on a specific case study of a medical tube manufacturing facility currently facing chronic efficiency bottlenecks during product changeovers. The existing extrusion die setup relies on a manual centering mechanism, where operators must adjust four fastening bolts to align the bushing and mandrel, as illustrated in Figure 1. However, the mechanical design is only part of the problem. As shown in Figure 2, the alignment process is heavily dependent on the operator's visual acuity and tactile skill to estimate gap uniformity. This "skill-based" approach is inherently unstable, leading to significant variations in setup time and product quality depending on individual operator experience. Initial baseline data revealed an average wall thickness deviation of 4.13%, which is unacceptably high for medical-grade standards.

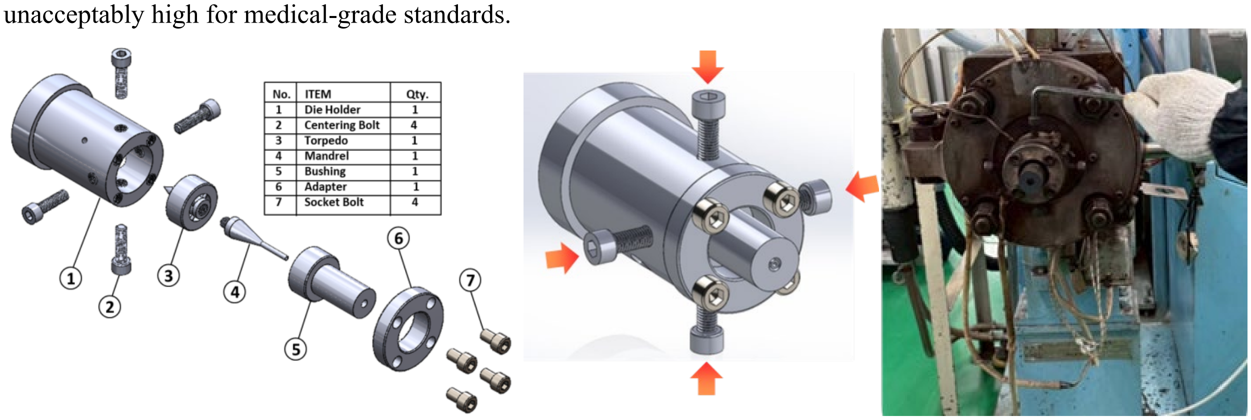

Figure 1. The conventional extrusion die assembly featuring the manual centering mechanism with four adjustment bolts.

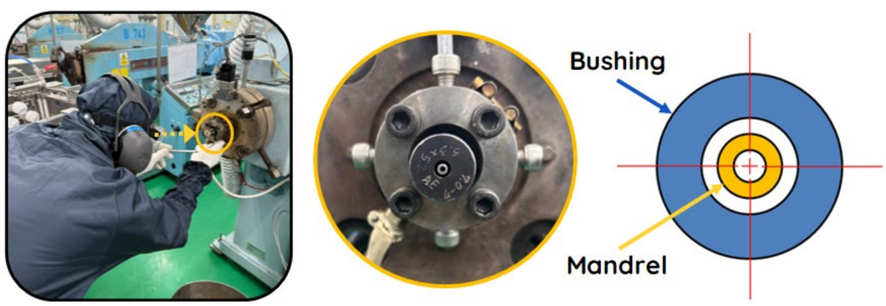

Figure 2. Operator performing the manual adjustment, highlighting the reliance on visual estimation and the difficulty of the task.

Furthermore, the choice of material for die components impacts long-term operational stability. The use of standard tool steel in the current setup has resulted in frequent surface oxidation and polymer burn marks, necessitating repetitive cleaning cycles that disrupt production flow. To address these multifaceted challenges, this study adopts a systematic approach following the Plan-Do-Check-Act (PDCA) cycle. The primary objectives are to eliminate human-dependent variables, reduce plastic waste generated during startup, and significantly shorten changeover duration. The proposed solution involves a strategic material upgrade to SUS420J2 stainless steel and the engineering of a novel self-centering die design (Die Model 2). By shifting from skill-based adjustment to design-based precision, this research aims to demonstrate a sustainable model for improving productivity and quality in medical tube extrusion.

2. Literature Review

To establish a robust framework for improving the medical tube extrusion process, this research synthesizes knowledge from three critical domains: die design mechanics, material science, and process management.

2.1 Die Design and Rheology Simulation Advanced flow analysis is fundamental to solving wall thickness inconsistencies. Rauwendaal (2014) established the core theory that flow imbalance in the runner system is the primary cause of variation, advocating for aerodynamic spider leg designs to minimize shear stress. Building on this, Lee et al. (2021) utilized Finite Element Analysis (FEA) to demonstrate that optimizing the mandrel and torpedo geometry can improve velocity distribution and reduce thickness deviation by up to 15%. Furthermore, studies by Kobayashi & Tanaka (2018) highlighted the correlation between die land length and polymer stress relaxation, which is crucial for controlling die swell. Petrov (2020) also emphasized that modifying the torpedo surface finish to promote laminar flow effectively mitigates melt fracture issues in HDPE pipes. These theoretical foundations directly influenced the design parameters of the "Die Model 2" proposed in this study.

2.2 Material Science and Maintenance The longevity and stability of extrusion tools are heavily dependent on material selection. Ahmed & Iqbal (2022) compared various die materials and found that high-hardness alloys with coatings like TiN can extend tool life by over 50% while reducing friction. This supports the decision to upgrade to SUS420J2 stainless steel to combat wear and oxidation. Regarding maintenance, Müller (2019) warned that microscopic carbonization buildup significantly affects flow stability, validating the need for the rigorous cleaning standards implemented in this research. Additionally, Wong & Lim (2022) proposed shifting from breakdown maintenance to preventive strategies to minimize downtime in SME manufacturing environments.

2.3 Process Management and Quality Control Integrating engineering solutions with management protocols is essential for sustainability. Chandra et al. (2021) showcased that Lean Six Sigma and DMAIC frameworks could reduce waste in PVC pipe manufacturing by 40%. To address human error in quality control, Chen & Wang (2019) developed real-time monitoring systems, which aligns with this study's objective of replacing subjective visual judgment with the Center Die Gauge. In the context of operational efficiency, Viriyaprakob (2020) demonstrated the effectiveness of SMED techniques in separating internal and external setup activities to drastically reduce changeover time in the Thai automotive industry.

3. Problem Formulation and Methodology

The primary challenge identified in this case study is the inherent instability of the medical tube extrusion process, specifically during the machine setup and changeover phases. The root cause of this inefficiency lies in the mechanical design of the existing die system. Currently, the concentricity between the bushing and the mandrel—which determines the uniformity of the tube's wall thickness—is controlled by a manual adjustment mechanism. This system requires operators to manipulate four fastening bolts to align the die components.

As illustrated in Figure 1 and Figure 2 (in the Introduction), this setup relies entirely on the operator's visual acuity and tactile skill to estimate the gap uniformity. This "trial-and-error" method is highly subjective and fundamentally flawed for precision manufacturing. Operators must iteratively tighten and loosen the bolts while observing the polymer flow, leading to a loop of adjustments that consumes excessive time. Data collected from five different operators revealed a significant variation in performance, with an average wall thickness deviation of 4.13%, indicating a lack of process repeatability. This variation results in the production of non-conforming tubes during the startup phase, generating substantial material waste. To analyze the root causes systematically, a Cause and Effect Diagram was constructed as shown in Figure 3.

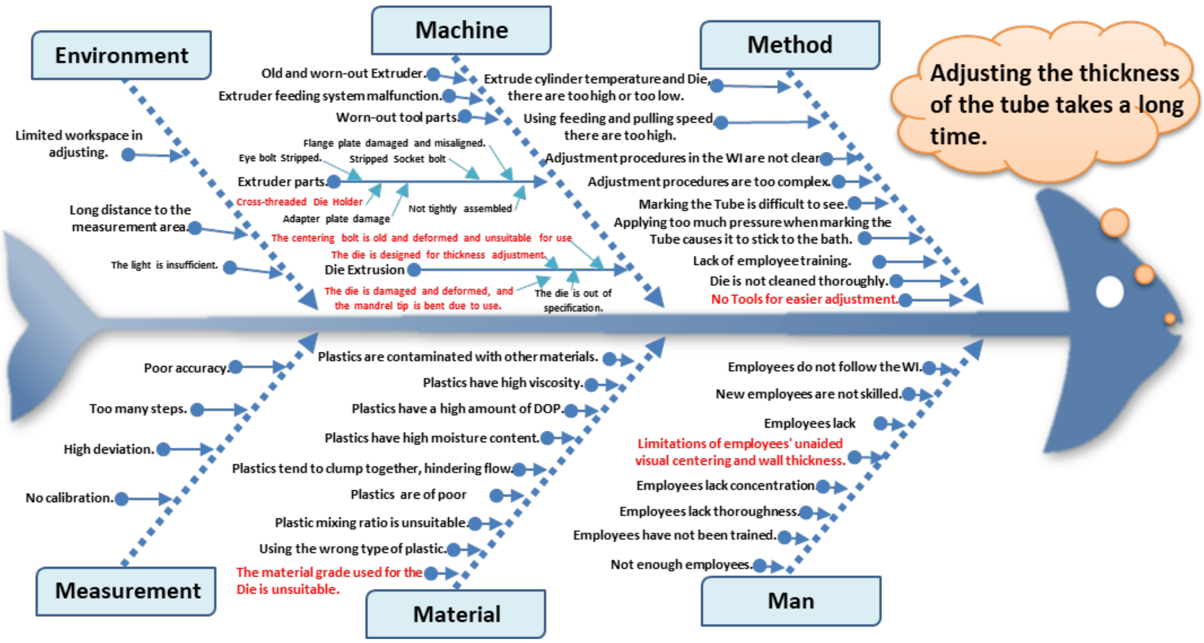

Figure 3. Identifying the root causes of wall thickness variation and prolonged setup time.

Compounding the mechanical issue is the material limitation of the die components. The existing tooling is manufactured from standard tool steel, which lacks sufficient resistance to the corrosive byproducts of polymer extrusion. Over time, the die surfaces suffer from oxidation and plastic deformation (wear), creating rough spots that accumulate polymer residue. This accumulation leads to "burn marks" or carbonized specks on the final product, necessitating frequent production stoppages for cleaning. The cleaning process itself is rigorous and risks further damaging the delicate die lips. Therefore, the formulation of the problem is twofold: the need to eliminate the dependency on human skill for centering, and the necessity to upgrade the material to withstand the harsh extrusion environment.

3.1 Research Framework

To ensure a robust and systematic approach to addressing the extrusion instability, this study developed an Integrated Engineering Design and Lean Optimization Framework (IED-LOF). Unlike traditional trial-and-error troubleshooting, this framework synthesizes mechanical design precision with iterative process improvement through the PDCA cycle. The methodology is structured into four distinct stages (Figure 4- Figure 10):

1. Diagnostic Stage: Utilizing Ishikawa diagrams and root cause analysis to decouple human variables from mechanical constraints, identifying the lack of a self-centering mechanism as the primary bottleneck.

2. Design-Engineering Stage: Transitioning from skill-based centering to design-based centering by implementing a fixed-geometry 'Socket and Spigot' architecture, coupled with advanced material selection (SUS420J2).

3. Validation Stage: Conducting rigorous data collection over 30 production lots to ensure statistical significance across key performance indicators, including setup time, material waste, and wall thickness deviation.

4. Economic Sustainability Stage: Translating technical improvements into financial impact analysis to verify the long-term viability of the proposed solution within a medical manufacturing environment.

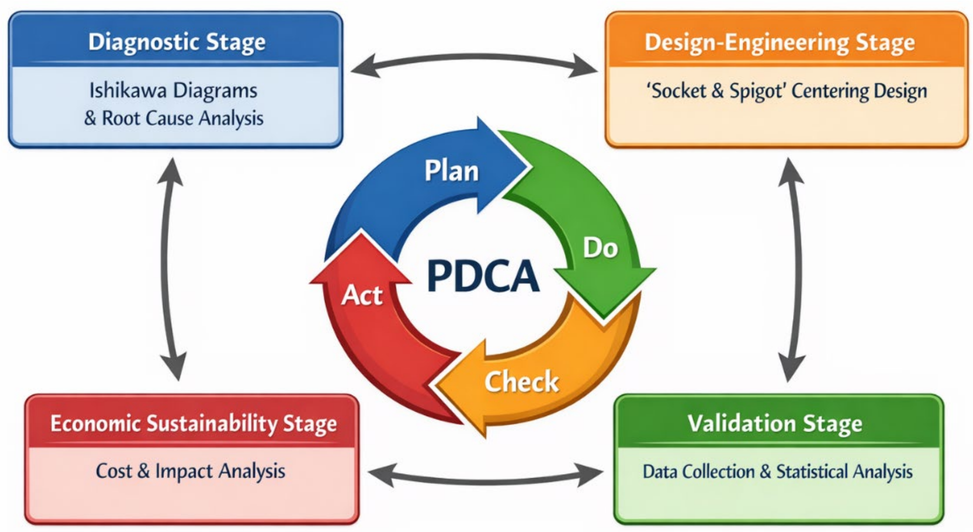

Figure 4. Integrated Research and Operational Framework (IED-LOF) showcasing the transition from problem identification to standardized solution.

3.2 Phase 1: Baseline Data Collection (Plan)

In the initial phase, historical data regarding setup time and material waste were collected over a period of three months. Time-motion studies were conducted to analyze the movement of operators during the die centering process. The analysis confirmed that the "adjustment loop" of the four fastening bolts consumed 60% of the total setup time.

3.3 Phase 2: Intermediate Improvement with Center Die Gauge (Do)

To address the subjectivity of visual alignment, a "Center Die Gauge" was introduced as an intermediate tool. This device was designed to provide a physical reference point for operators when centering the bushing and mandrel. While it did not eliminate the manual bolts, it converted the alignment process from a purely visual judgment to a gauge-assisted method. This phase served as a proof of concept that standardizing the gap measurement could reduce deviation.

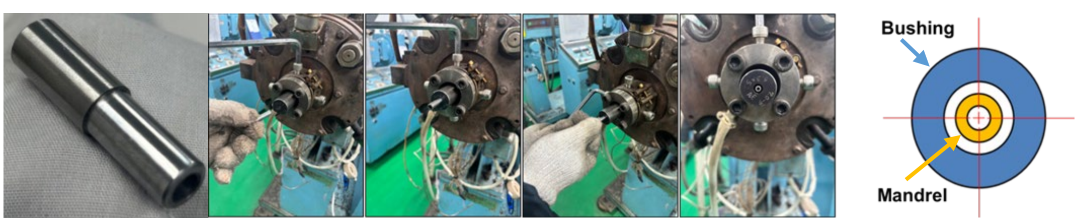

Figure 5. Application of the Center Die Gauge to assist in manual alignment, reducing reliance on visual estimation.

3.4 Phase 3: Advanced Engineering Design – Die Model 2 (Do)

The core innovation of this study was the development of "Die Model 2," a self-centering extrusion die. Unlike the conventional design, Die Model 2 utilizes a fixed-geometry fit between the die body and the mandrel holder, completely eliminating the four adjustment bolts.

- **Mechanical Design:** The design employs a precision "Socket and Spigot" joint architecture. This ensures that the concentricity is determined by the machining tolerance of the steel rather than operator adjustment. The flow channel was also hydro-dynamically optimized to reduce shear stress on the polymer melt. The development of the self-centering mechanism involved an iterative engineering refinement. Initially, a precision clearance fit of H7/g6 was implemented for the 'Socket and Spigot' joint. However, empirical testing during the prototype phase indicated that this tolerance class still allowed for marginal mechanical play, which could lead to subtle concentricity errors. Consequently, the final design was optimized to a tighter H6/h6 fit, ensuring absolute centering stability between the mandrel and bushing. To complement this precision, a surface roughness requirement of 6.3 Ra or better was mandated for all mating surfaces to ensure repeatable assembly accuracy and minimize micro-frictional variances.

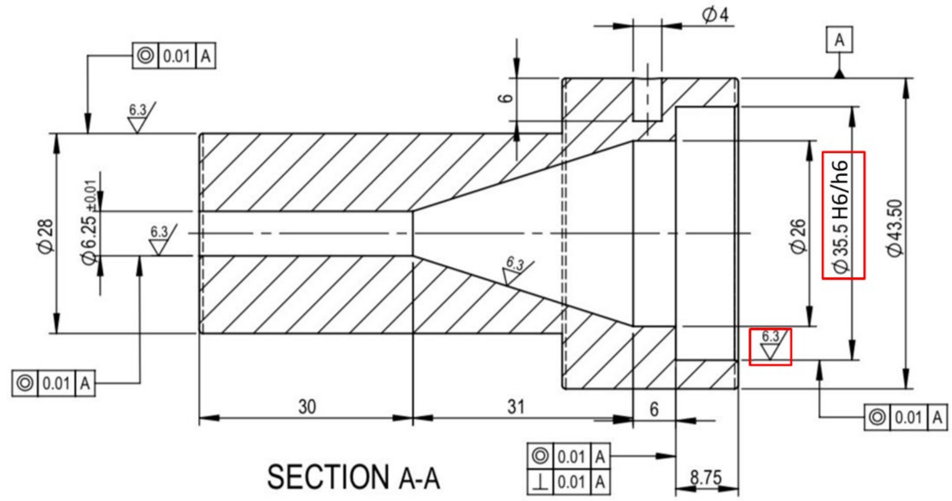

Figure 6. Technical drawing of the bushing component illustrating the precision-machined surfaces and the H6 tolerance specification for the self-centering interface.

- **Material Optimization:** To combat the corrosion and wear issues identified in the problem formulation, the die material was upgraded from standard tool steel to SUS420J2 Stainless Steel.
- **Heat Treatment:** The new die components underwent a vacuum heat treatment process to achieve a surface hardness of 52-54 HRC. This specific hardness range was selected to maximize wear resistance against the abrasive nature of medical-grade polymers while maintaining sufficient toughness to prevent brittle fracture during assembly.

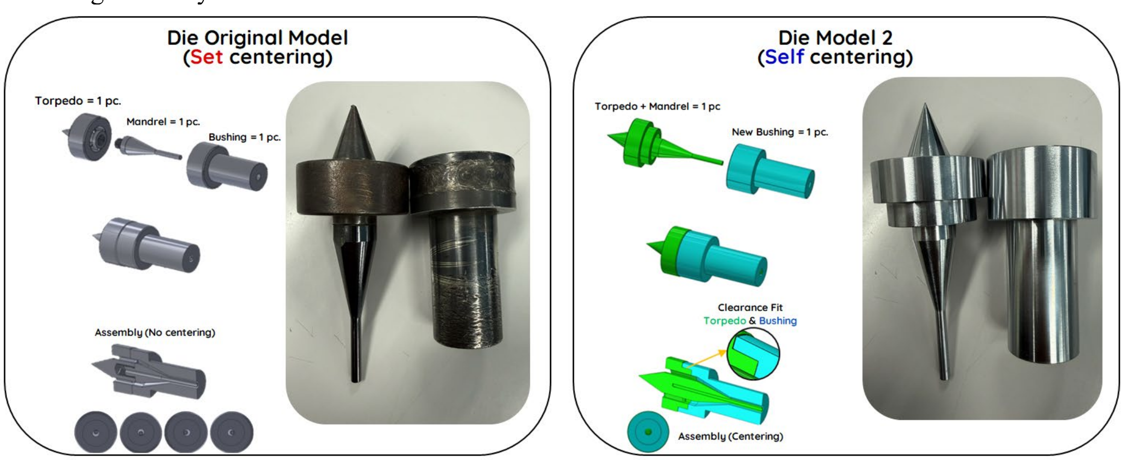

Figure 7. Comprehensive comparison between the Original Die Model (left) showing complex assembly and material degradation, versus the newly developed Self-Centering Die Model 2 (right) featuring simplified fixed-geometry design and corrosion-resistant SUS420J2 material.

3.5 Phase 4 & 5: Implementation and Evaluation (Check & Act)

The fabricated Die Model 2 was installed on the extrusion line for a controlled production run. Performance metrics including setup time, startup waste (kg), and wall thickness deviation were recorded and compared against the baseline data. Finally, the new setup procedure was standardized into the company's Work Instruction (WI) to ensure long-term sustainability.

4. Data Collection

To ensure statistical validity and comprehensive analysis, data collection was conducted under controlled industrial conditions. The data gathering process was segmented into two primary phases: the pre-improvement baseline (utilizing the original die and manual methods) and the post-improvement phase (utilizing the Center Die Gauge and Die Model 2). Four Key Performance Indicators (KPIs) were established to measure the effectiveness of the proposed solutions:

4.1 Operational Procedure and Time

The die setup process was recorded using high-resolution video analysis to capture every motion of the operators. This footage was then deconstructed to count the total number of operational steps and identify non-value-added activities. Simultaneously, a calibrated stopwatch was used to measure the total setup time, defined as the duration from the cessation of the previous production lot to the production of the first tube that meets all quality specifications (First Good Part).

4.2 Material Waste

Polymer waste generated during the changeover was categorized into two types: "Setup Waste" (material purged during cleaning and assembly) and "Startup Waste" (material extruded during the centering adjustment phase). The waste from each category was collected and weighed using a digital industrial scale with a precision of ±0.01 kg to calculate the total material loss per lot.

4.3 Quality Metrics (Wall Thickness Deviation)

The concentricity of the produced medical tubes was assessed by measuring the wall thickness deviation. Samples were collected from each experimental lot, and thickness was measured at eight equidistant points around the tube's circumference using a high-precision digital micrometer. The percentage of thickness deviation was calculated to monitor process capability. Additionally, a Gauge Repeatability and Reproducibility (Gauge R&R) study was performed to validate the precision of the newly developed Center Die Gauge, ensuring that the measurement system itself was reliable before full-scale implementation.

4.4 Economic and Productivity Metrics

To validate the commercial viability of the improvement, operational costs related to machine downtime and material wastage were calculated based on the collected data. Productivity rates were also analyzed to determine the overall efficiency gain of the production line.

5. Results and Discussion

5.1 Numerical Results

The implementation of the proposed improvements yielded significant quantitative enhancements across all targeted Key Performance Indicators (KPIs). The comparison between the baseline data (traditional method) and the post-improvement data (using Die Model 2) reveals a substantial reduction in operational complexity. Specifically, the number of setup steps was reduced from 23 to 15 steps, effectively eliminating 8 non-value-added activities associated with the manual adjustment of fastening bolts.

This process streamlining directly translated into time and material savings. The average machine setup time decreased by 9.33 minutes per lot, representing a major improvement in machine availability. Regarding material efficiency, the total plastic waste generated per changeover was reduced by 7.88 kg. This figure is composed of a 3.00 kg reduction during the setup phase (due to easier cleaning of the SUS420J2 surface) and a 4.88 kg reduction during the startup phase (due to the elimination of trial-and-error centering). Table 1 summarizes the quantitative impact of the self-centering die implementation.

Table 1. Comparison of operational metrics between the traditional method and the proposed improvement (Die Model 2).

Key Performance Indicators (KPIs)	Unit	Traditional Method (Before)	Proposed Method (After)	Improvement (Delta)
Operational Steps	Steps	23	15	**-8 Steps**
Average Setup Time	min / lot	45	35.67	**-9.33 min**
Total Material Waste	kg / lot	19.88	12.00	**-7.88 kg**
Thickness Deviation	%	4.13	2.08	**-2.05%**

As detailed in Table 1, the distinct improvement in operational steps directly contributed to a reduction in Average Setup Time from 45.00 to 35.67 minutes per lot. Furthermore, the Total Material Waste dropped significantly from 19.88 kg to 12.00 kg per changeover. Quality-wise, the Thickness Deviation was minimized from 4.13% to 2.08%, confirming that the process capability has surpassed the initial standard.

5.2 Graphical Results

To visualize the magnitude of these improvements, comparative analysis was conducted for the key metrics:

- Setup Time & Material Waste: The reduction in setup time and material waste is visually represented in Figure 8 and Figure 9, respectively. These charts highlight the efficiency gained by eliminating manual adjustments.

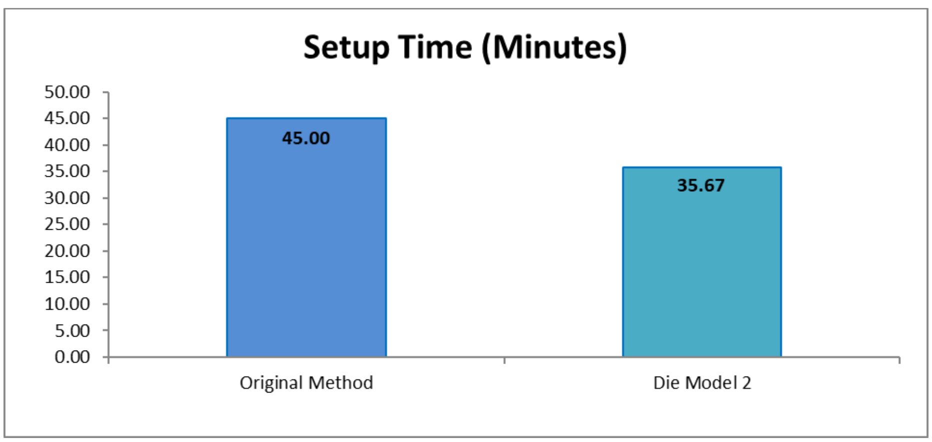

Figure 8. Comparison of average setup time (minutes) before and after improvement.

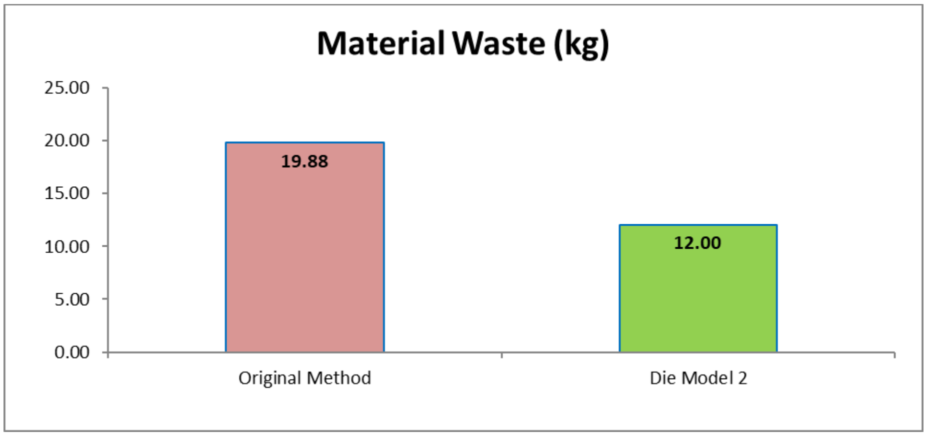

Figure 9. Comparison of material waste (kg) generated during the startup phase.

- Wall Thickness Deviation Analysis: To visualize the improvement in product quality, the wall thickness deviation was monitored throughout the research phases. Figure 10. illustrates the progressive reduction in deviation, clearly demonstrating the impact of each engineering intervention:

  Phase 1 (Baseline): The process exhibited a high fluctuation with an average deviation of 4.13%, attributed to human variation.

  Phase 2 (Center Die Gauge): The introduction of the gauge reduced the deviation to 2.74%, stabilizing the process but still requiring manual intervention.

  Phase 3 (Die Model 2): The implementation of the self-centering die further minimized the deviation to 2.08%.

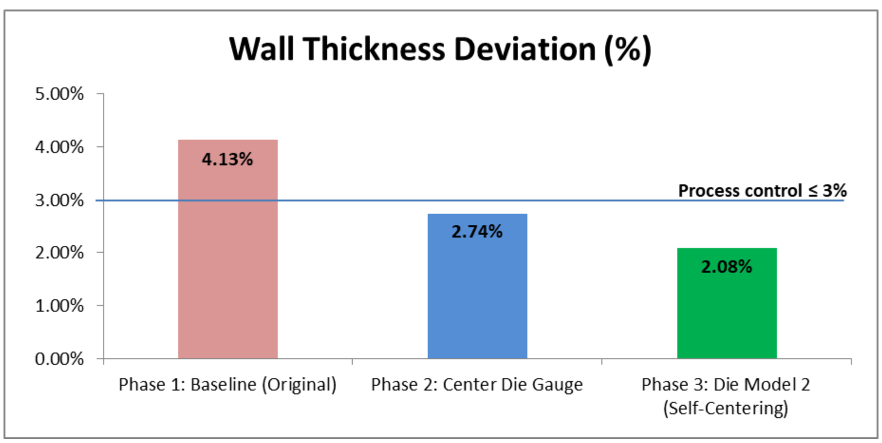

Figure 10. Comparison of wall thickness deviation across the three implementation phases.

As shown in Figure 10, the final result not only surpasses the previous performance but also falls well within the strict tolerance limits required for medical-grade tubing. The downward trend confirms that shifting from a skill-based process to a design-based constraint effectively stabilizes product quality.

5.3 Proposed Improvements

The realized improvements discussed above are the direct result of two specific engineering solutions proposed and implemented in this study:

1. Material Upgrade: The transition to SUS420J2 stainless steel proved effective in mitigating surface degradation. Post-production inspection revealed a significant reduction in burn marks and oxidation spots compared to the original tool steel die. This improvement extended the cleaning cycle interval and reduced the effort required for die maintenance.

2. Self-Centering Mechanism: The Die Model 2 design successfully replaced the variable "floating" alignment of the bushing and mandrel with a "fixed" geometrical fit. This mechanical constraint ensures that concentricity is achieved automatically upon assembly, validating the hypothesis that design-based centering is superior to skill-based adjustment.

5.4 Discussion of Engineering Factors

The technical success of Die Model 2 is rooted in the elimination of the 'Mechanical Tolerance Stack-up'. While the initial design utilized an H7/g6 fit, the transition to an H6/h6 precision fit was the decisive factor in achieving a wall thickness deviation of only 2.08%. By narrowing the fundamental deviation, the design effectively 'locks' the mandrel into a true-center position, removing the possibility of human-induced misalignment. Furthermore, the specification of a 6.3 Ra surface finish ensures that the interface between components is uniform, preventing 'micro-tilting' during assembly a common issue in lower-precision dies. This evolution from skill-based adjustment to a high-precision, fixed-geometry design is what fundamentally stabilized the extrusion process.

Furthermore, the material transition to SUS420J2 significantly alters the Surface Energy and Thermal Degradation profile of the PVC melt during stagnation. The chromium-rich oxide layer of the stainless steel prevents the catalytic degradation of PVC, which was a frequent cause of 'carbon specks' and material buildup in the original tool steel die. This phenomenon explains the recorded 3.00 kg reduction in cleaning-related waste. Because the stainless steel surface maintains its integrity under high temperatures, the polymer flow remains laminar and free from surface-adhesion issues, ensuring long-term process stability without the need for frequent stoppages.

5.5 Validation

To validate the economic feasibility and sustainability of the proposed improvements, a cost-benefit analysis was conducted. The reduction in raw material waste (7.88 kg/lot) and the decrease in non-productive machine time contributed to a total cost saving of 11,300.65 THB per month. This calculation accounts for both the direct material cost savings and the indirect labor and machine depreciation costs during the setup and cleaning processes. The consistent performance of the Die Model 2 over consecutive production lots further validates that the solution is robust and suitable for long-term industrial application.

5.6 Managerial Implications

The findings of this research provide critical insights for manufacturing excellence in the medical device industry, offering benefits that extend beyond simple technical improvements:

- De-skilling the Process: By embedding critical centering 'skill' directly into the 'design' of the tooling (a form of Poka-Yoke or error-proofing), the organization significantly reduces its vulnerability to high labor turnover and the inherent variability of human performance. This ensures that production quality remains consistent regardless of the operator's experience level.

- Quality Risk Mitigation: In medical manufacturing, wall thickness consistency is not merely a cost factor but a fundamental patient safety requirement. The reduction in thickness deviation to 2.08% ensures strict compliance with international standards such as ISO 13485. This mitigates the risk of product recalls and strengthens the company's reputation for reliability.

- Resource Efficiency and Sustainability: The 3.1% increase in line productivity demonstrates that significant gains in manufacturing sustainability can be achieved by optimizing existing equipment through precision engineering. This approach allows the company to increase capacity without the need for capital-intensive new machinery, optimizing the Return on Investment (ROI) for existing assets.

6. Conclusion

This research successfully achieved its primary objectives of enhancing production efficiency and reducing material waste in the medical tube extrusion process. Through the systematic application of the PDCA cycle and advanced engineering design, the study addressed the root causes of process instability: operator dependency and equipment degradation.

The development and implementation of the Die Model 2 with a self-centering mechanism proved to be a decisive solution. By eliminating the manual adjustment requirement, the setup process was streamlined from 23 to 15 steps, and the average setup time was reduced by 9.33 minutes per lot. The transition to SUS420J2 stainless steel further contributed to process stability by minimizing surface oxidation and cleaning downtime.

Quantitatively, the improvements resulted in a significant reduction of total plastic waste by 7.88 kg per changeover and improved product quality, with wall thickness deviation decreasing from 4.13% to 2.08%. These operational enhancements translate into a monthly cost saving of 11,300.65 THB, confirming the economic viability of the proposed design.

In conclusion, this study demonstrates that replacing human-dependent variables with precision engineering controls is the most effective strategy for high-standard manufacturing. The self-centering die design not only resolves immediate production bottlenecks but also establishes a sustainable standard for future medical device manufacturing.

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