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Research article

ENHANCING PROCESS STABILITY AND QUALITY MANAGEMENT: A COMPREHENSIVE ANALYSIS OF PROCESS CAPABILITY INDICES

Aleksy Kwilinski and Maciej Kardas

Abstract. Process Capability Indices such as Process Capability Index (Cp) and Corrected Process Capability Index (Cpk), along with Process Performance Index (Pp) and Process Performance Corrected Index (Ppk), are most commonly used tools in quality management within manufacturing processes. They determine whether a process is capable of producing products within established tolerance limits, addressing both short-term and long-term variability. Despite widespread use, the analysis of Process Capability Indices often overlooks special variability within processes, which may lead to misleading interpretations of a process's capability, especially when the determination of tolerance limits is inadequately conducted. This article aims to verify the hypothesis that current analyses of Process Capability Indices fail to consider special variability, which could mislead the interpretation of a process's ability to meet its specifications. Statistical analyses were conducted using the Minitab software, based on dynamic viscosity measurements from the production process of solvent-based paint, to explore the implications of special variability on the interpretation of Process Capability Indices. The study revealed that while Process Capability Indices are useful for identifying quality management opportunities, their effectiveness is limited when special variability is present, often resulting in misinterpretations of a process's true capabilities. The findings highlight the need for methodologies that incorporate considerations of all forms of variability to ensure accurate process capability assessments. This gap in traditional analyses can affect the strategic decision-making in quality management, suggesting a critical area for further research and methodological development. The research confirms the need for a revised approach in analyzing Process Capability Indices, advocating for advanced methods that accurately reflect all forms of variability to improve quality management practices. Future research should focus on developing these methodologies to ensure more reliable and effective use of Process Capability Indices in quality management.

Keywords: quality management, stability, process capability indices, Process Capability Index (Cp), Corrected Process Capability Index (Cpk), Process Performance Index (Pp), Process Performance Corrected Index (Ppk), long-term variability, short-term variability, dynamic viscosity

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Author(s):

Aleksy Kwilinski
The London Academy of Science and Business, 120 Baker St, London W1U 6TU, UK
E-mail: a.kwilinski@london-asb.co.uk
https://orcid.org/0000-0001-6318-4001

Maciej Kardas
Faculty of Applied Sciences, WSB University, 41-300 Dabrowa Gornicza, Poland
E-mail: kardas.maciej@wp.pl
https://orcid.org/0009-0008-9910-7380

Corresponding author: Maciej Kardas, kardas.maciej@wp.pl

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1. Introduction

In the philosophical landscape, the relationship between quality and quantity reveals a fundamental dialectic: while quality describes the attributes or characteristics that define the essence of an object, quantity determines the measurable aspects that give structure to those qualities. This interplay is pivotal in understanding any subject matter, including the realm of quality management in manufacturing processes, which is the focus of our study.

Quality, as discussed in various philosophical doctrines, is not merely an inherent trait but is perceived and validated through its quantitative expressions. This concept holds a significant position in manufacturing and production, where quality cannot exist in the abstract but must be quantifiable to ensure standards are met and maintained. Therefore, in the broader philosophical context, our discussion transcends the operational details of manufacturing to touch upon an essential truth: the manifestation of quality is inherently linked to its quantifiable aspects. Without quantity, quality remains an abstract concept, elusive and impractical. By grounding the philosophical abstraction of quality in the quantitative reality of process capability indices, we bridge the gap between theory and practice, providing a comprehensive framework that enhances both the understanding and implementation of quality management strategies. This synthesis is crucial for developing robust quality control systems that not only aspire to high standards but also achieve them consistently, thereby fostering reliability and trust in manufacturing processes.

Quality is a key issue in the functioning of enterprises, their production processes, and the products manufactured. In many cases, it is also defined as a measure of effective enterprise functioning in a cascading approach.

Quality, defined as a component of the characteristics and properties of products, but also processes and services meeting specific guidelines and potential needs [1,2]. A very important issue is the comparative aspect of quality and productivity. To ensure high productivity, the quality of the processes conducted or products manufactured must be somewhat reduced. Similarly, productivity will be reduced when efforts to improve quality are intensified. To ensure an appropriate level of both parameters: quality and productivity, it is necessary to undertake optimization efforts [3]. Quality is also recognized as a direction building competitive advantage for companies and organizations in the global market. It should be emphasized that over time, the understanding of quality has evolved significantly. Starting from basic methods of inspection, through quality control, quality assurance, to contemporary quality management concepts and philosophies [4].

Process capability indices such as Process Capability Index (Cp), Corrected Process Capability Index (Cpk), Process Performance Index (Pp) and Process Performance Corrected Index (Ppk) are fundamental tools in the area of quality management, especially in the production layer, but also in industrial processes [5,6]. They define values that allow determining the capabilities of production processes, indicating whether the obtained values fall within designated specifications and tolerances; this is a key aspect for maintaining high quality of products and services. Thus, they allow determining the efficiency of the process [7-10], and also estimating the probability that as a result of the processes conducted, products will be produced in accordance with requirements [11]. In general, process capability indices allow determining the quantitative relationship between the actual performance of the process and the given product specifications [12].

The potential capability index, Cp measures the ability of a process to produce products within specified tolerance limits without considering the position of the process mean relative to these limits. In contrast to the potential capability index, the actual capability index Cpk takes into account the position of the process mean relative to the tolerance limits. Pp, similar to Cp, measures the ability of a process to produce within specification limits, but unlike the potential capability index, which uses short-term process variability, Pp refers to long-term variability. A similar trend is observed in the comparative analysis between the Ppk and Cpk indices. Ppk, like Cpk, considers both the spread and the centering of the process, but for long-term variability. It is an indicator that best reflects the actual performance of the process over time [13].

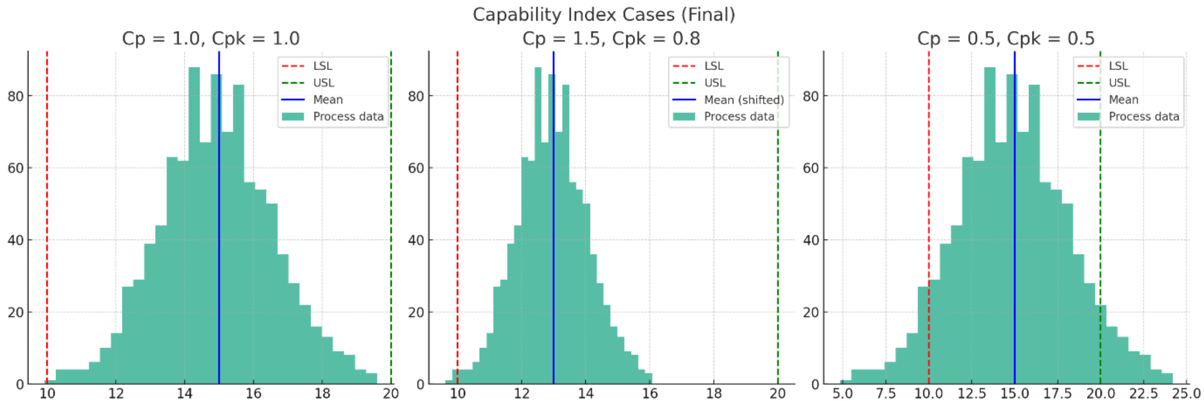

Figure 1. Scenarios Regarding Process Capability Indices
Source: own elaboration.

The charts illustrate three scenarios regarding process capability indices: Cp and Cpk:

- Cp=Cpk=1: scenario represents a process that is just capable of meeting the specification limits, with its distribution centered between the limits. It indicates that the process is performing at the threshold of acceptability with minimal margin for error.
- Cp>1 and Cpk<1: case shows a process that, while theoretically capable due to a high Cp, has a practical performance issue as indicated by Cpk<1, likely due to a shift or spread in the process mean away from the target value, demonstrating a need for process adjustment to improve performance.
- Cp=Cpk=0.5: illustrates a process that is not capable of consistently meeting the specification limits, with significant variability and/or mean shift from the target. Both Cp and Cpk being less than 1 indicate a process in need of substantial improvement.

Each chart includes a histogram of process data, with lines indicating the Lower Specification Limit (LSL, red dashed line), Upper Specification Limit (USL, green dashed line), and the process mean (blue solid line).

As we conclude this introductory exploration of the philosophical underpinnings and practical applications of quality within various industrial and organizational frameworks, it is clear that the journey towards understanding and implementing robust quality management strategies is both necessary and complex. The transition from theoretical aspects to empirical analysis forms the bridge that leads us to the next sections of this paper, where we will apply these concepts in a detailed examination of process capability indices.

This exploration is not just about the technical assessment of these indices but also about situating them within the broader narrative of quality management practices that are continuously evolving in response to new challenges and innovations. The forthcoming sections aim to dissect these challenges methodically, employing rigorous methodologies to uncover the nuances of process capability and its impact on operational excellence. We will delve into the materials and methods that guide our analysis, followed by a presentation of results that both confirm and challenge existing paradigms. This will set the stage for a robust discussion where theoretical insights and empirical findings intersect, leading to conclusions that we hope will contribute meaningfully to the field of quality management and beyond.

2. Literature Review

The quest for excellence in modern business practices places a strong emphasis on quality as a pivotal element that transcends various dimensions of organizational operations. The scholarly discourse surrounding quality management is rich and varied, illustrating how this concept has evolved and expanded across different industries and borders. As one delves into the literature, an array of scientific articles is found that not only highlight the significance of quality but also explore the strategic implementations that enhance organizational competitiveness globally. These studies provide profound insights into the dynamic nature of quality management, revealing how it is shaped by innovations and the ever-changing expectations of the market and society.

This section of our research synthesizes key findings from numerous sources that collectively underscore the critical role of quality as a competitive advantage and a benchmark for operational excellence. Whether through the lens of process capability indices or the broader framework of quality control, the literature presents compelling arguments and evidence supporting the integral role of quality in achieving superior performance and sustainability in business practices.

Thus, in the literature collections, numerous scientific articles [13-18] emphasize the importance of quality. The global orientation of companies, processes, and most importantly – organization employees, has led to the creation of many strategies and innovative trends in the aspect of quality management concepts [19,20].

In the article [21], author points out that quality is a distinguishing feature of a product among competitors. Moreover, in many cases, quality is defined as a feature for which investors should be willing to pay a higher price [16].

Process capability indices play an important role in the aspect of quality management and are widely used to investigate the product potential, as well as to determine the process capability, in order to increase the actual performance of the process based on previously defined tolerance ranges [22]. In the article [23], author draws attention to the fact that process capability indices define statistics related to quality control. They are used to assess the ability to monitor the process, and also play an important role in the area of quality control, due to the fact that they quantitatively determine the relationship between the actual performance of the process and the given product specifications. In publication [24], the multi-level application of process capability indices was emphasized, directing thought to the fact that they can be used in areas dedicated to both production and business activities.

There are many publications that define process capability indices as a key direction in the context of understanding process behavior, but also as a solution that significantly facilitates its analysis, and consequently, its control. Their significant impact means that they are used in many sectors of the industry: pharmaceutical [13,25,26], automotive [27-29], food [30,31], and others [32-34].

Recent studies expand the conversation about quality management and its implications across various sectors, highlighting innovative approaches and global perspectives. Szczepańska-Woszczyna et al. [35] explore the relationship between public health efficiency and country competitiveness, suggesting that the principles of quality management extend beyond manufacturing and into public health, affecting overall national competitiveness during the pre-pandemic and pandemic periods.

Chen et al. delve into the green development of countries and the role of macroeconomic stability, aligning environmental initiatives with quality management frameworks to ensure sustainable development [36]. This study underscores the necessity of integrating quality management with green policies to enhance macroeconomic stability.

Hussain et al. provide empirical evidence from Thailand on the impact of globalization and economic growth on ecological footprints, linking quality management practices directly with sustainable global practices [37]. The research points to the need for quality management to encompass environmental considerations, which are increasingly crucial for global business operations.

Dacko-Pikiewicz's examination of family business branding within stakeholder-oriented value frameworks presents an angle of quality management that is closely tied to branding and stakeholder satisfaction, essential components for long-term business success [38].

Moreover, Kwilinski's exploration of blockchain technology in the accounting sphere represents a significant advancement in how quality management principles are applied in financial operations, ensuring transparency and efficiency [39].

These studies collectively emphasize that the scope of quality management and process capability indices is vast and intersects with numerous aspects of modern business and societal challenges. They advocate for a holistic approach to quality management that not only focuses on manufacturing processes but also incorporates broader economic, environmental, and technological dimensions. This alignment with global standards and innovative management practices ensures that the application of process capability indices remains relevant and effective in a rapidly evolving business environment.

By integrating these diverse perspectives into the existing body of literature on quality management and process capability indices, the article enriches the discourse and provides a comprehensive view of the challenges and solutions in modern quality management practices. These insights are crucial for developing robust strategies that leverage quality management to enhance operational efficiency and competitiveness across sectors.

Continuing with the integration of interdisciplinary insights, further exploration into the interaction between digital transformation and quality management reveals critical dynamics shaping industries today.

Authors [40] analyze the pivotal role of digitalization in enhancing Environmental, Social, and Governance (ESG) performance within firms, highlighting that digital tools can drive the efficiency and transparency required for improved quality management practices. The authors illustrate how technologies such as ESG reporting software and data analytics platforms can bolster the capability of businesses to meet higher standards of quality and sustainability.

Further, the exploration of green finance and its spillover effects on sustainable development by [41] points to the increasing importance of financial strategies that support environmental and quality goals. They employ a Spatial Durbin Model to demonstrate how green finance initiatives can enhance process capabilities across industries, suggesting that financial policy and quality management are interlinked and mutually reinforcing.

In the context of specific industrial applications, [42] discusses the reduction of CO2 emissions in the transport sector through environmental technologies and renewable energy. Their research underlines the necessity for quality management systems to adapt and integrate eco-friendly technologies to not only comply with regulatory demands but also improve process efficiency and sustainability.

In article [43], author also emphasizes the significant impact of the development of digital technology - including artificial intelligence - in the area of carbon dioxide emissions, within the framework of quality management systems.

The authors of publication [44] focus on the global energy landscape, which is evolving towards green energy solutions, emphasizing the importance of strategic management in the realm of quality management.

In addition to the articles described, many sources in scientific publications discuss quality management strategies to improve environmental aspects or to identify factors that have a significant impact on them [45-47].

Adding a perspective on the impact of the COVID-19 pandemic, [48] examine how the crisis has reshaped investment markets in Central and Eastern Europe. Their findings suggest that quality management practices must be dynamic and responsive to external shocks to maintain process stability and performance in uncertain times.

Moreover, embracing the broader implications of country branding on environmental, social, and governance performance, [49] provides insights into how national strategies and digitalization efforts can be harmonized to boost a country’s green brand and enhance its international competitiveness. This study amplifies the importance of strategic alignment between quality management and national policy initiatives.

Publication [50] is focused on analyzing the effectiveness of marketing actions used by Polish and Czech cultural institutions. The study aimed to understand respondents' opinions on the effectiveness of these actions, suggesting that there is a relationship between the quality of these actions and relationships with cultural offer recipients.

Dacko-Pikiewicz [51], in her publication, points out that in the context of quality management an important element is strategic analysis and identification of areas for improvement, which was done in this study by analysing the strategic documents of the city of Cieszyn-Český Těšín and conducting in-depth interviews with the directors of local cultural institutions. The results of the study identified a gap in these documents, which concerned the need to intensify joint cultural activities between Poland and the Czech Republic. This gap in the strategy can be interpreted as a deficiency in quality management, as there is no clear indication of the development of a cross-border market for cultural services.

Through these diverse explorations across sectors and themes, it becomes evident that the principles of quality management are continually evolving to incorporate advanced technologies, environmental considerations, and broader socio-economic factors. The integration of these perspectives into the framework of process capability indices not only enriches the academic dialogue but also provides practical pathways for businesses and policymakers to enhance their operational and strategic approaches. This holistic view is essential for fostering a resilient and sustainable future, where quality management practices are not only about maintaining standards but also about driving innovation and embracing global challenges.

This expanded narrative underscores the necessity of integrating cutting-edge research and varied sectoral insights into the discourse on quality management, highlighting the dynamic and interconnected nature of modern industrial practices.

Despite the extensive exploration of process capability indices in the literature, a significant gap remains in understanding their application in the presence of special variability. Many studies generalize the effectiveness of these indices without addressing how special variability can affect the accuracy of process capability assessments. This oversight can lead to misinterpretations, potentially skewing the perceived quality and performance of processes. Our research aims to address this gap by focusing on the real-world application of these indices when confronted with non-standard variability, offering a critical reevaluation of their role in quality management systems. This effort will help standardize methodologies across different industrial settings, ensuring more robust and adaptable quality control practices.

The central issue and goal within this research area is to verify the hypothesis that the analysis of process capability indices does not incorporate special variability, occurring within the analyzed process. Additionally, it is postulated that this analysis can generate a wrong interpretation of results, especially in situations where the determination of process tolerance limits has been conducted inadequately. This study will focus on a detailed identification of circumstances in which process capability indices present the highest reliability and usefulness. Subsequently, based on the collected data, recommendations for an optimal utilization strategy of these indices will be developed. The overarching direction is to minimize the risk of incorrect data interpretation, by considering the impact of special variability and precisely defining the tolerance limits of processes. This initiative aims not only to strengthen the reliability of the used process capability indices but also to increase the efficiency of production processes through better adaptation to actual operational conditions.

The structure of this article is designed to provide a comprehensive exploration of process capability indices and their effectiveness within quality management frameworks. Following this literature review, the subsequent sections will delve deeper into the specifics of our study. Section 3, "Materials and Methods," outlines the quantitative and qualitative research strategies employed, including the statistical tools and methodologies that underpin our analysis. Section 4, "Results," presents the empirical findings from our case study, highlighting how process capability indices perform under various operational scenarios and their impact on quality control. Section 5, "Discussion," interprets these results, discussing their implications for current quality management practices and addressing the limitations identified in previous studies. Finally, Section 6, "Conclusions," synthesizes the insights gained from our research, offering recommendations for enhancing the application of process capability indices and suggesting directions for future research. This structure is crafted to ensure a logical flow of information, facilitating a clear understanding of how process capability indices can be optimized to improve the robustness and reliability of quality management systems in diverse manufacturing environments.

3. Materials and Methods

The research covered in terms of demonstrating the benefits and limitations resulting from the use of process capability indices as a tool used in the layer of control of their processes corresponds both to the nature of quantitative research strategies, but also qualitative ones. The data analysis was based on the statistical program Minitab 21.4.1; a package being a collection of programs created to conduct analyses with a high degree of numerical accuracy. It is based on Automated Machine Learning for binary and continuous responses based on Predictive Analytics Module [52]. The software is designed specifically for business-focused operations, offering user’s convenient methods to input statistical data, manipulate it, identify patterns and trends, and ultimately analyze the data to address real-world problems. It streamlines data analysis, making it ideal for statistical interpretation at the business level. Minitab offers a range of visual tools such as histograms, boxplots, and scatterplots, which aid professionals in conducting statistical analysis more efficiently and gaining insights from their data. Additionally, it empowers users to compute descriptive statistics for their datasets.

The current trend in the development of statistical software indicates that Minitab is the most well-known commercial application in the field of implementing Lean Six Sigma projects [53].

To ensure that the methodologies employed in this study adhere to the highest standards of quality and reliability, the procedures were aligned with internationally recognized ISO standards, specifically ISO 9001. This alignment provides a structured framework that enhances the credibility of the process assessments and supports the consistency of the results, crucial for validating the effectiveness of process capability indices in quality management.

The case study in reference to the hypothesis stated in this publication, aimed at defining the limitations and benefits resulting from the use of process capability indices, is based on the analysis of dynamic viscosity data, constituting one of the critical parameters for the process of producing single-component solvent-based paints.

The methodological rigor imposed by compliance with ISO 9001 ensures that every aspect of the production process—from the calibration of equipment to data collection and analysis—meets stringent quality control standards, thus bolstering the integrity of the findings.

Limitations of reasoning occurring in the conducted research study: one laboratory technicians responsible for performing physicochemical measurements of the controlled product, measurement conducted using one viscometer: Brookfield DV-E. Before starting the tests, the samples were each time thermostated to a temperature of 23°C ± 0.5. The dynamic viscosity measurement was performed using spindles – sp3 or sp4 (depending on final viscosity of the batch), in cans with a capacity of 1 liter. The viscosity parameter was noted 30 seconds after starting the device. Paint batches are produced in a complex production process consisting of several successive stages, conducted on one dissolver with consideration of two operators.

It should be noted that the dataset analyzed in this article is of a primary nature. Moreover, it corresponds to the total variability of the process for the period from March 2022 to June 2023. This comprehensive approach, guided by ISO 9001 standards, not only ensures the reliability of the process measurements but also enhances the generalizability of the study results across similar industrial settings.

4. Results

The results section presents a quantitative analysis, enriched with elements of qualitative analysis in the aspect of process capability indicators. The conducted research study shows sequentially following actions aimed at defining direct benefits, but also limitations resulting from the implementation of the described indicators in the quality management layer of the production process.

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4.1. Boundary Conditions; Data Distribution

The premise of the histogram (Figure 2), in the context of the case study conducted, was to show the data distribution – dynamic viscosity, in relation to the assumed time interval of analysis. During the specified data collection period, a total of 35 batches were produced. It should be assumed that the lower process tolerance limit for the obtained product was 600 mPa·s, while the upper limit was set at 800 mPa·s. The presented set of values, in a holistic view, takes the form of a normal distribution. For the application of process capability indicators to be possible, it is necessary to prove the occurrence of the Gaussian distribution within the analyzed data [11,54]. In the absence of confirmation, there is a high probability of incorrect interpretation of the obtained results. The assumption of the normality of the distribution of process quality characteristics is fundamental in the context of analyzing process capability in terms of the described indicators.

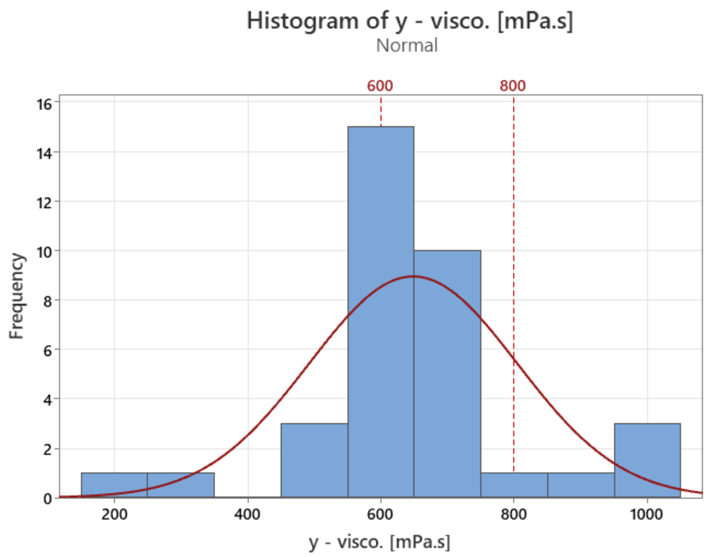

Figure 2. Histogram of the Analysed Values over the Period March 2022 to June 2023
Source: own elaboration.

Figure 3 - The time series plot presents a complete distribution of data taking into account the actual sequence of received values. Observations shown on the chart below (Figure 3), emphasize the fact of their random arrangement – absence of visible trends or characteristic patterns. In the case of the occurrence of described premises, advanced analysis of input data becomes necessary. Thoughtless interpretation of obtained values in the aspect of individual process capability indicators can then lead to erroneous conclusions.

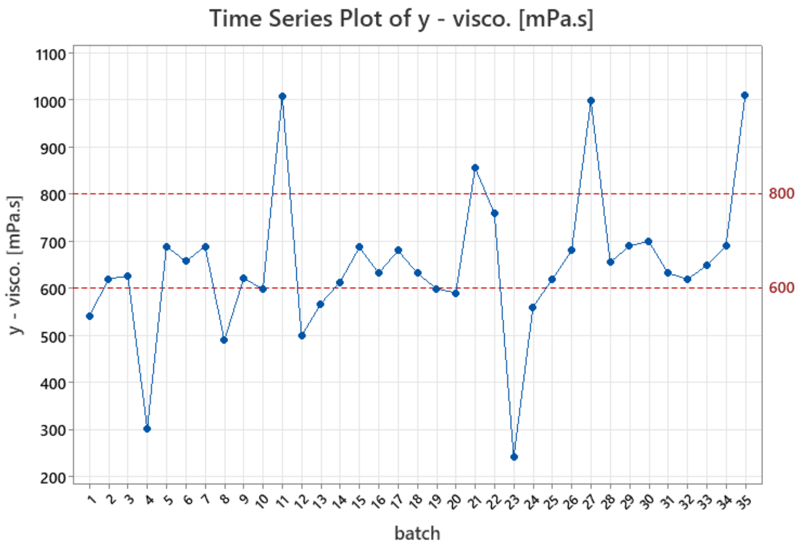

Figure 3. Time Series Plot of the Analysed Values over the Period March 2022 to June 2023
Source: own elaboration.

4.2. Process Capability Indicators

Based on the data collected in the process, using the Minitab software, a Process Capability Report (Figure 4) was created, which presents the values of individual parameters and process capability indicators corresponding to the examined production process.

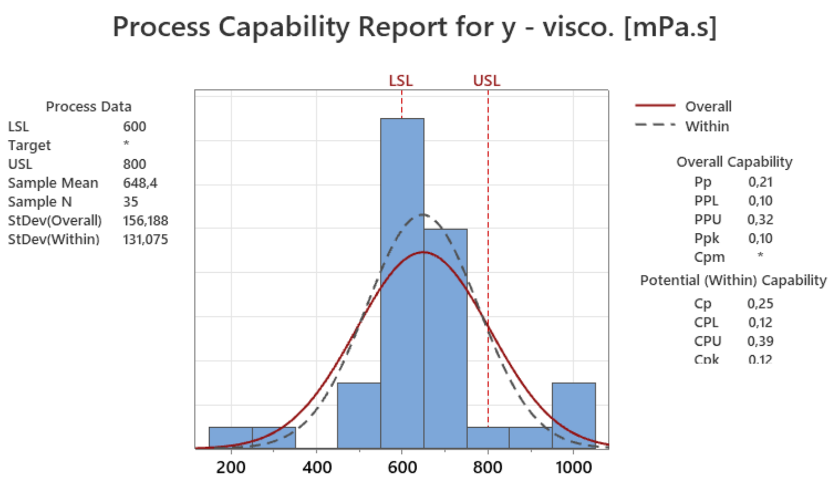

Figure 4. Process Capability Report
Source: own elaboration.

Details in terms of calculating the values of individual process capability indicators – Cp, Cpk [55], Pp, and Ppk [56] are presented in the equations below:

$$\mathrm{Cp} = \frac{(\mathrm{USL}-\mathrm{LSL})}{6\sigma} = \frac{(800-600)}{6\cdot 131.08} = 0.25 \quad (1)$$

$$\mathrm{Cpk} = \min\left(\frac{\bar{x}-LSL}{3\sigma}, \frac{USL-\bar{x}}{3\sigma}\right) = \min\left(\frac{648.4-600}{3 \cdot 131.08}, \frac{800-648.4}{3 \cdot 131.08}\right) = \min(0.12, 0.39) \quad (2)$$

$$\mathrm{Pp} = \frac{(\mathrm{USL}-\mathrm{LSL})}{6s} = \frac{(800-600)}{6 \cdot 156.19} = 0.21 \quad (3)$$

$$\mathrm{Ppk} = \min\left(\frac{\bar{x}-LSL}{3s}, \frac{USL-\bar{x}}{3s}\right) = \min\left(\frac{648.4-600}{3 \cdot 156.19}, \frac{800-648.4}{3 \cdot 156.19}\right) = \min(0.10, 0.32) \quad (4)$$

Due to the fact that the data distribution in the normal distribution is shifted towards the lower specification limit, the values for the Cpk and Ppk indicators should be taken as the results obtained from the following calculations: $\frac{\bar{x}-LSL}{3\sigma}$ for Cpk and $\frac{\bar{x}-LSL}{3s}$ for Ppk; results - 0.12 and 0.10.

The values of the process capability indicators in the context of the analyzed research study have taken the following dimensions:

Cp; a value of 0.25 is very low and indicates that the process spread is significantly wider than the design tolerances. Cpk; a value of 0.12 defines that the process not only has a large spread but is also shifted relative to the nominal value. This means that a large portion of production does not meet the established quality parameters. Pp; a value of 0.21 suggests that the overall performance of the process is low in the context of meeting design specifications, taking into account both spread and shift. Ppk; a value of 0.10 is very low, indicating that considering the shift of the mean from the target value, the process is even less capable of producing parts within specification limits than the spread (Pp) suggests.

To be able to calculate the above indicators, it is necessary to determine the value of the estimated standard deviation (σ) in the Cp and Cpk indicators, according to the formula below:

$$\sigma = \frac{\overline{MR}}{d_2} \quad (5)$$

where $\overline{MR}$ is the average of the absolute differences between successive measurements, and d_2 is a constant, which for individual measurements equals 1.128 [57]. To determine the average moving range $\overline{MR}$, the simplest solution is to prepare an I-MR chart (Figure 5). Additionally, the individual value and moving range chart allow us to determine whether there are alarming signals in the process in relation to potential special variability.

The moving range chart (Figure 5) indicates two points exceeding the value of the UCL (Upper Control Limit), which unequivocally confirms the occurrence of two special variabilities in the process. Additionally, based on the processed data, the individual value chart defines that in the process, within the natural variability, we can expect values ranging from 255.2 to even 1041.6 mPa·s. Data falling within the indicated range do not constitute special variability. The obtained values unequivocally challenge the validity of the adopted process tolerance limits: 600 – 800 mPa·s. The actual variability of the process is significantly greater.

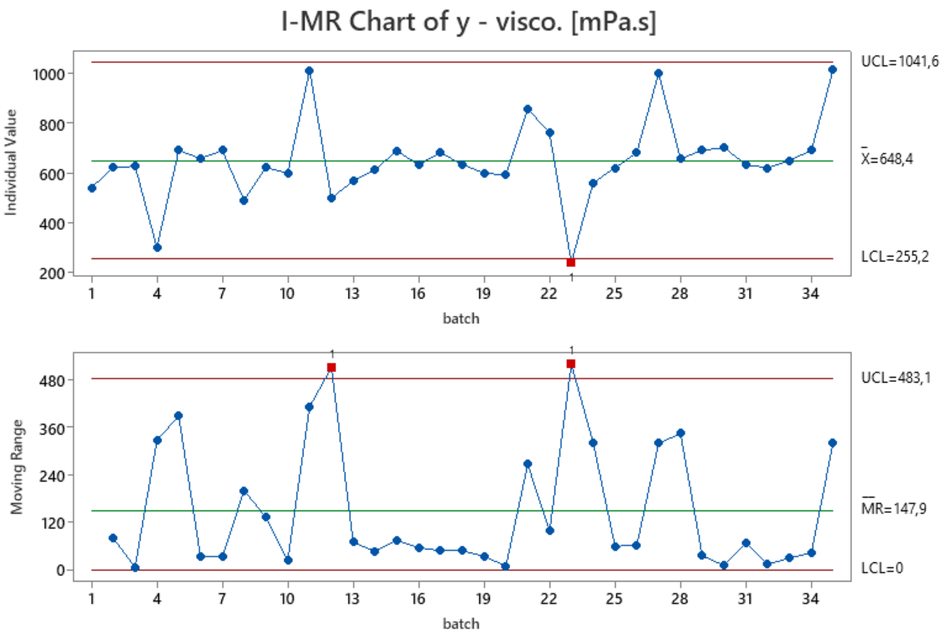

Figure 5. I-MR Chart
Source: own elaboration.

In the case of Pp and Ppk indicators, which characterize long-term variability, it is necessary to refer to the global (overall) standard deviation (s), determined by the formula:

$$s = \sqrt{\frac{\sum(x_n - \bar{x}\ bar)^2}{n-1}} \quad (6)$$

The sample variance is the sum of the squares of differences between each observation x and the sample mean $\bar{x}$, divided by n-1, where n is the number of observations.

5. Discusssion

The results obtained in the conducted case study represent a valuable source of information regarding the benefits and barriers of using process capability indices. It is important to remember that each research work has certain limitations and shortcomings, which are attributed to the lack of complete objectivity in reflecting the specificity of the scientific area under study.

The authors of publications [58-61] pay special attention to the fact that process capability indices are an important tool in the area of quality management of manufacturing processes. The content of article [58] emphasizes that the use of process capability indices is characterized by a relatively high level of uncertainty, mainly due to the fact that any error in the sample can introduce significant uncertainty into the process capability assessment. In publications [61,62], the authors emphasize that for the possible use of process capability indices for correct data analysis, the occurrence of a normal distribution in the collected values is necessary. The author of article [62] also emphasizes that the assumptions about the normality of distribution are often untrue.

Article [63] presents a methodology based on Johnson's transformation to convert non-Gaussian distribution data to enable the analysis of process capability indices (PCIs). This method is particularly useful when the quality characteristics of the process do not meet the assumption of normal distribution. The content of publication [64] focuses on the application of an improved Box-Cox transformation model to convert non-Gaussian distribution data and calculate process capability indices. Article [65] proposes new solutions in the area of process capability indices for continuous data with a non-Gaussian distribution. The new indices are a generalization of the classical ones, offering a consistent quantification of process capability for both normal and non-Gaussian distributions. The authors discuss non-parametric and parametric estimation of the proposed indices.

The analyzed literature indicates a significant development in the aspect of process capability indices, so as to fully limit the possibility of incorrect data analysis, which consequently could lead to incorrect conclusions.

However, the critical examination of statistical assumptions underlying process capability indices is paramount, as these assumptions directly influence the validity of the indices' application. The reliance on normal distribution assumptions, as noted in previous studies, can mislead quality assessments when the actual data distribution deviates from normality. This underscores the importance of employing statistical transformations, such as Johnson's or Box-Cox transformations, to adapt the data to fit these assumptions better [66-68]. However, even with transformations, the risk of oversimplification remains if the intrinsic properties of the process variability are not accurately captured. Therefore, it is recommended that future applications of these indices include robust sensitivity analyses to gauge the impact of assumption violations on the indices' interpretations and conclusions.

Moreover, adherence to and integration of global quality standards, such as those from the International Organization for Standardization (ISO), specifically ISO 9001, play a crucial role in the successful deployment of these advanced systems. These standards provide a solid framework for quality assurance that complements the technical capabilities of process capability indices. By aligning process capability assessments with ISO standards, organizations can ensure that their quality management systems are robust, compliant, and capable of achieving international quality benchmarks.

The potential of process capability indices to contribute to a dynamic quality management system is significantly enhanced when integrated with real-time monitoring and feedback mechanisms. Such integration allows for the immediate application of corrective actions, which is particularly valuable in continuous production environments where process drifts can occur unnoticed over time. Real-time data analysis can help identify these shifts sooner, enabling adjustments before deviations lead to significant quality degradation. The development of intelligent monitoring systems that can interpret process capability data and initiate responses autonomously could be a significant step forward, reducing reliance on periodic manual reviews and adjustments.

6. Conclusions

The conducted research study provides significant information in terms of the hypothesis set as the main goal of the publication. Data analysis unequivocally confirms the validity of using process capability indices, allowing at the same time to assess whether the process is capable of producing within specified tolerance limits. However, it should be noted that the use of indices, which are the subject of this publication, carries many limitations in the proper interpretation of the obtained results.

Process capability indices enable the improvement of quality and efficiency of manufacturing processes. They also allow for easy identification of problems, which contributes to the implementation of appropriate corrective actions. They provide quantifiable data, based on the holistic behavior of the process.

Based on the analysis conducted, the main limitation to be emphasized is that process capability indices are not capable of indicating special variabilities, which pose a huge problem in terms of proper analysis of process data. Furthermore, they are calculated taking into account the lower and upper specification limits, which do not reflect the natural variability of the process, thus creating a dissonance between the actual variability of the process and the adopted tolerance limits. To properly define the real variance distribution in terms of individually collected data, it is necessary to prepare an individual value chart and a moving range (I-MR). The fundamental assumption remains that process capability indices are only an element of a broad quality management system, which means that they require supplementation with additional analyses and tools that enable a complete data analysis.

Moreover, the findings advocate for an update to the industry standards regarding process capability indices. It is essential to adapt these standards to include considerations for natural process variability and special variabilities. Such updates will enhance the reliability of quality assessments, particularly in high-precision industries such as pharmaceuticals and automotive manufacturing.

Process capability indices should not be used in isolation. They must be part of a comprehensive quality management system. We recommend the development of integrated frameworks that combine these indices with other diagnostic tools like statistical process control (SPC) charts and Six Sigma methodologies. This approach will help in achieving a more comprehensive monitoring and improvement of process quality.

Furthermore, the study's outcomes underscore the need for an alignment of process capability indices with the International Organization for Standardization (ISO) standards, particularly ISO 9001, which focuses on Quality Management Systems. Adapting process capability indices to conform with ISO 9001 can ensure that the indices not only measure but also enhance the quality management process in accordance with internationally recognized best practices. This adaptation should include incorporating ISO's requirements for ongoing process improvement and risk-based thinking into the application of process capability indices. By doing so, organizations can better manage and reduce the discrepancies identified between assumed and actual process variabilities. Future updates to ISO standards could benefit from incorporating findings from this research, suggesting a need for standards that more explicitly address the nuances of process capability in various manufacturing environments. Such integration would facilitate a more holistic approach to quality management, ensuring that standards and practices remain relevant and robust in the face of evolving industry challenges.

Further research should focus on creating more adaptive process capability indices that can dynamically reflect changes in process conditions and material properties. Additionally, exploring the use of artificial intelligence and machine learning to predict process deviations before they exceed acceptable limits could revolutionize process control technologies.

To maximize the benefit of process capability indices, we suggest the implementation of targeted training programs for quality control professionals. These programs should focus on advanced statistical methods and the interpretation of process capability data, ensuring that personnel are well-equipped to implement these tools effectively.

The advancement in real-time data collection technologies offers significant potential for improving the application of process capability indices. Adopting such technologies would allow for the continuous adjustment of processes, leading to improved product quality and process efficiency.

Finally, we emphasize the strategic value of process capability indices in corporate decision-making. These indices provide critical insights that can guide decisions related to process adjustments, resource allocation, and quality improvements, ultimately leading to enhanced operational efficiency and competitiveness.

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