Risk-based Statistical Evaluation of Absorbable P(LA/CL) Barbed Suture Manufacturing Processes

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Abstract. Absorbable surgical sutures produced from poly(L-lactide–ε-caprolactone) (P(LA/CL)) copolymers are critical medical devices in aesthetic and reconstructive procedures, where consistent dimensional and mechanical performance directly impacts patient safety. This study presents a comprehensive risk-based statistical evaluation of five APTOS barbed suture product lines with respect to United States Pharmacopeia (USP) requirements, integrating industrial quality engineering methods into medical device manufacturing assessment. A total of 96 samples per product line were analyzed for suture diameter, length, needle attachment strength, and tensile strength. The methodology included normality testing, confidence interval estimation, and statistical process capability analysis (Cpk), with appropriate transformations applied for non-normal data. Results indicated highly capable diameter processes, varied length conformity across products, and critical variability in needle attachment strength, including multimodal failure distributions. Tensile strength results were interpreted in terms of process consistency rather than regulatory non-compliance due to testing configuration nuances. By framing pharmacopeial criteria within process capability and risk-based quality paradigms, this study demonstrates how statistical quality tools support regulatory readiness and continuous manufacturing improvement of absorbable sutures.

Keywords: absorbable sutures; statistical process capability; quality risk management; USP compliance; manufacturing variability

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1 Introduction

Absorbable surgical sutures are essential medical devices used in a wide range of surgical and aesthetic procedures. Their clinical performance depends directly on dimensional consistency, mechanical integrity, and compliance with pharmacopeial standards. In particular, barbed sutures manufactured from poly(L-lactide–ε-caprolactone) (P(LA/CL)) copolymers have gained increasing popularity due to their favorable balance between tensile strength, elasticity, and biodegradation behavior.

Compliance with United States Pharmacopeia (USP) requirements is a prerequisite for market authorization and safe clinical application of absorbable sutures. USP chapters <861> and <881> define acceptance criteria and standardized testing methods for suture diameter, length, needle attachment strength, and tensile strength. While conformity testing confirms compliance at a given point in time, it does not provide insight into long-term process stability or manufacturing robustness.

Statistical process capability analysis offers a quantitative framework for evaluating how consistently a manufacturing process meets specification limits. Metrics such as the process capability index (Cpk), combined with normality testing and confidence interval estimation, enable identification of latent quality risks and support evidence-based process improvement.

The objective of this study is to perform a comprehensive statistical baseline evaluation of five APTOS absorbable barbed suture product lines manufactured from sterile P(LA/CL) copolymer. The analysis focuses on assessing compliance with USP requirements, identifying statistically significant nonconformities, and highlighting manufacturing stages that require optimization. By transforming an industrial test dataset into a structured scientific analysis, the study aims to contribute applied evidence to quality engineering practices in medical device manufacturing.

2. Literature Review

Quality assurance of medical devices is governed by international regulatory and standardization frameworks, among which the United States Pharmacopeia (USP) plays a central role in defining acceptance criteria for surgical sutures. USP chapters <861> and <881> establish standardized test methodologies and quantitative thresholds that manufacturers must satisfy to ensure clinical safety and performance. Within industrial engineering research, compliance with such standards is increasingly interpreted through a risk-based and capability-oriented lens rather than binary pass–fail assessment [1].

Statistical process capability analysis is widely applied in quality and industrial engineering to evaluate manufacturing robustness. Indices such as Cpk and Ppk provide normalized measures of process centering and dispersion relative to specification limits [2]. Numerous studies demonstrate that high capability indices are correlated with reduced nonconformance rates and improved long-term process stability, particularly in high-reliability manufacturing sectors including medical devices [3].

Recent research emphasizes that biomedical manufacturing processes frequently exhibit non-normal data distributions, especially for mechanically sensitive characteristics such as component length, bonding strength, and attachment integrity. Such behavior has been reported for polymer-based medical products due to tooling tolerances, viscoelastic material response, and measurement system effects [6]. To address these challenges, transformation-based statistical modeling approaches, including Box–Cox and Johnson transformations, are commonly recommended to enable valid capability estimation under non-normal conditions [5].

In the context of surgical sutures, existing literature predominantly focuses on material composition, degradation kinetics, and clinical outcomes of absorbable polymers such as polylactide, polycaprolactone, and their copolymers [7] [8]. Studies addressing mechanical performance typically emphasize tensile strength and knot security; however, fewer investigations examine manufacturing variability and process capability using industrial statistical methods.

Needle attachment strength has been identified as a critical-to-quality characteristic due to its direct impact on functional reliability and patient safety. Failure modes such as suture pullout or grip-related rupture are recognized sources of quality risk in assembled medical devices [9]. Quality engineering studies highlight that multimodal or bimodal strength distributions often indicate the presence of special causes and necessitate targeted root-cause analysis rather than global process adjustment [10].
From a quality engineering and industrial management perspective, baseline statistical evaluation serves as a foundational element of continuous improvement and regulatory readiness. Capability-based analysis enables prioritization of corrective actions, supports evidence-based decision-making, and aligns with modern quality risk management principles embedded in standards such as ISO 13485 and ISO 14971 [11] [12]. The present study contributes to this body of knowledge by applying established industrial statistical quality methods to a large-scale dataset obtained from routine manufacturing of absorbable P(LA/CL) barbed sutures, thereby addressing a gap between

materials-focused research and process-oriented quality engineering literature.

3. Materials and Methods

3.1 Evaluated Products

Five APTOS absorbable barbed suture product lines were evaluated:

- Excellence Visage (EV)
- Excellence Elegance (EE)
- Excellence Body (EB)
- Light Lift Thread 2G Soft (LLT2GS)
- Light Lift Needle 2G Soft Large (LLN2GSL)

All products were manufactured from sterile poly(L-lactide–ε-caprolactone) (P(LA/CL)) copolymer and designed for aesthetic and reconstructive applications [13].

3.2 Sampling Strategy

For each product line, 96 suture units were randomly selected from representative manufacturing lots. This sample size was chosen to provide sufficient statistical power for estimation of distribution characteristics, confidence intervals, and process capability indices [13]. Where applicable, data from multiple lots were aggregated to assess overall process behavior.

3.3 Evaluated Parameters

The following quality characteristics were analyzed in accordance with USP requirements:

- Suture diameter
- Suture length
- Needle attachment strength (where applicable)
- Tensile strength

Acceptance limits were defined strictly based on USP specifications for size 2-0 and size 0 sutures.

3.4 Statistical Analysis

The statistical evaluation included:

- Normality testing using p-value analysis supported by histogram inspection;
- Estimation of 95% confidence intervals for means and standard deviations;
- Process capability analysis using the Cpk index;

Let X denote a random variable representing a measured quality characteristic (e.g., diameter, length, or strength). Assuming that X follows a distribution with mean μ and standard deviation σ, the process capability index C_{pk} is defined as:

$$C_{pk} = \min\left(\frac{USL-\mu}{3\sigma}, \frac{\mu-LSL}{3\sigma}\right)$$

where USL and LSL denote the upper and lower specification limits defined by USP requirements.

Under the assumption of a stationary and normally distributed process, the probability of nonconformance can be expressed in terms of tail-area probabilities as: $P(X < LSL \text{ or } X > USL) = \Phi\left(\frac{LSL-\mu}{\sigma}\right) + 1 - \Phi\left(\frac{USL-\mu}{\sigma}\right)$

where $\Phi(\cdot)$ denotes the cumulative distribution function of the standard normal distribution. Consequently, low or negative values of C_{pk} mathematically imply a non-zero probability of nonconforming output even in the absence of special causes.

- Estimation of expected nonconformance rates expressed as Defects Per Million (DPM).

For data sets exhibiting significant deviation from normality, appropriate transformations (e.g., Box–Cox or Johnson transformations) were applied prior to capability analysis to ensure valid modeling of process behavior.

For datasets exhibiting significant deviation from normality, direct estimation of σ leads to biased capability estimates. Therefore, a monotonic transformation $T(X)$ was applied such that $T(X) \approx \mathcal{N}(\mu_T, \sigma_T^2)$, preserving order statistics while enabling valid parametric inference for capability analysis.

4. Results

4.1 Suture Diameter

All evaluated product lines demonstrated full compliance with USP diameter requirements. Mean diameter values were well centered within specification limits, and no individual measurements exceeded the upper or lower bounds. From a quality engineering perspective, the observed process

capability indices (Cpk > 3.5) indicate a highly robust and well-centered process with minimal variability relative to specification width. Such capability levels are typically associated with mature, well-controlled manufacturing processes and imply a negligible risk of future nonconformance.

Table 1 presents the descriptive statistics and process capability indices (Cpk) for suture diameter, confirming highly capable and well-centered processes across all evaluated product lines.

Table 1. Descriptive statistics and process capability indices for suture diameter across evaluated product lines

Product	Mean (mm)	SD (mm)	Cpk
EV	0.381	0.006	3.68
EE	0.376	0.005	4.07
EB	0.387	0.005	4
LLT2GS	0.38	0.005	4.1
LLN2GSL	0.381	0.004	2.11

4.2 Suture Length

Suture length performance varied significantly across product lines, revealing clear differences in process maturity. Excellence Visage, Excellence Elegance, and Excellence Body sutures exhibited Cpk values greater than 1.33, corresponding to capable and stable processes under conventional industrial quality criteria. These results indicate that the cutting and measurement stages for these products are effectively controlled.

Table 2. Suture length statistics and USP conformity assessment.

Product	Mean (mm)	SD (mm)	Cpk
EV	191	1.77	1.44
EE	127.5	2.42	1.85
EB	241.6	0.58	7.84
LLT2GS	242.1	2.44	0.62
LLN2GSL	471.7	3.49	-0.32

In contrast, Light Lift Thread 2G Soft exhibited a marginal process capability (Cpk ≈ 0.62), indicating that the process operates close to the lower specification limit and is sensitive to common-cause variation. From a risk-based quality standpoint, such a process is vulnerable to drift and may generate nonconforming output without additional controls. The most critical condition was observed for Light Lift Needle 2G Soft Large, where a negative Cpk value indicates that the process mean lies below the specification limit. This behavior reflects a systemic mismatch between manufacturing output and labeled requirements rather than isolated defects.

As shown in Table 2, while Excellence Visage, Excellence Elegance, and Excellence Body exhibit capable length processes (Cpk > 1.33), Light Lift Thread 2G Soft and Light Lift Needle 2G Soft Large demonstrate marginal and non-capable performance, including a negative Cpk value.

4.3 Needle Attachment Strength

Needle attachment strength represents a critical-to-quality characteristic due to its direct influence on functional reliability. For Light Lift Thread 2G Soft, the process demonstrated compliance with USP requirements but exhibited limited robustness (Cpk < 1.0), suggesting that variation reduction or process centering would be beneficial to reduce long-term quality risk.

Table 3. Needle attachment strength statistics and failure mode comparison.

Product	Mean Strength (N)	Cpk
LLT2GS	14.23	0.91
LLN2GSL (FM1&2)	12.74	1.31
LLN2GSL (FM3)	4.66	-0.04

As shown in Table 3, while LLT2GS and LLN2GSL (failure modes 1 and 2) demonstrate compliance with USP requirements, the pullout-dominated failure mode (FM3) exhibits a negative Cpk value,

indicating a non-capable and unstable attachment process.

For Light Lift Needle 2G Soft Large, the presence of three distinct failure modes resulted in a bimodal strength distribution. From a quality engineering standpoint, this behavior is indicative of an unstable process influenced by special causes. Failure modes corresponding to suture rupture near the grip satisfied USP criteria, whereas the suture pullout mode exhibited severe nonconformance. Such bimodality strongly suggests variability in needle attachment integrity and highlights the necessity of root-cause analysis and corrective action to eliminate the pullout mechanism.

From a statistical modeling perspective, the observed strength distribution can be represented as a mixture distribution:

$$f(x) = \pi_1 f_1(x) + \pi_2 f_2(x),$$

where $f_1(x)$and $f_2(x)$correspond to distinct failure mechanisms and π_1, π_2 denote their respective mixing proportions. Under such conditions, global process capability indices are not directly interpretable unless the data are stratified by failure mode.

4.4 Tensile Strength

Multiple tensile failure modes were observed across all evaluated product lines, including mid-suture rupture and grip-related failures. Statistical comparison indicated no significant differences between failure modes, supporting the conclusion that the observed tensile strength variability reflects inherent material and process behavior rather than isolated anomalies. As discussed, the tensile strength results are interpreted as indicators of process consistency rather than definitive regulatory compliance metrics.

5. Discussion

From a quality and industrial engineering perspective, the presented results enable classification of the evaluated manufacturing processes into distinct capability categories. Suture diameter processes across all product lines qualify as highly capable and robust, indicating effective control of extrusion and diameter-forming operations.

Suture length analysis reveals a progression from capable to unstable processes, emphasizing the importance of aligning specification limits with actual process performance. Marginal and negative Cpk values observed for selected products represent elevated quality risk and justify targeted interventions, such as process centering, equipment recalibration, or reassessment of labeled specifications.

Mathematically, a negative value of C_{pk} indicates that the expected value of the process output lies outside the admissible specification interval, implying inevitable nonconformance under stationary process assumptions.

Needle attachment strength emerges as the most critical risk area due to its sensitivity to assembly conditions and failure mode variability. The identification of bimodal distributions underscores the value of failure-mode-based statistical analysis for detecting hidden process instability that may not be evident from average values alone.

Overall, the integration of statistical process capability analysis with pharmacopeial requirements provides a powerful framework for risk-based quality management in medical device manufacturing. The results demonstrate how capability indices, when interpreted within an industrial engineering context, support proactive decision-making, regulatory readiness, and continuous process improvement.

The statistical results confirm that suture diameter manufacturing processes are highly stable and well controlled. In contrast, suture length and needle attachment strength exhibit product-dependent variability, revealing critical quality risks. In particular, systematic under-length production and

needle pullout failure modes represent significant compliance concerns that warrant targeted root-cause analysis and process optimization.

The application of process capability analysis proved effective in distinguishing between isolated nonconformities and systemic process deficiencies. These findings demonstrate the importance of integrating statistical quality tools into routine medical device manufacturing and regulatory surveillance.

Future research should focus on detailed root-cause analysis of non-capable processes identified in this study, particularly those related to suture length variability and needle attachment pullout failure modes. Advanced failure mode and effects analysis (FMEA) combined with design of experiments (DoE) may be applied to isolate critical process parameters influencing attachment integrity. In addition, longitudinal statistical process control (SPC) studies are recommended to assess long-term stability and drift under routine manufacturing conditions. The integration of real-time monitoring and automated quality analytics could further enhance early detection of special causes and support predictive quality management. Extending the proposed capability-based framework to other absorbable polymer systems and suture sizes would also strengthen its general applicability in medical device manufacturing and regulatory compliance assessment.

6. Conclusions

This study employed statistical process capability analysis as a quantitative framework for evaluating the conformity and robustness of absorbable P(LA/CL) barbed suture manufacturing processes with respect to United States Pharmacopeia specifications. By combining descriptive statistics, confidence interval estimation, distributional assessment, and capability index evaluation, the analysis enabled a mathematically grounded characterization of process behavior beyond binary compliance assessment.

The results demonstrated that suture diameter processes exhibit exceptionally high capability indices (Cpk > 3), reflecting minimal dispersion relative to specification limits and strong process centering. From a statistical standpoint, such values indicate a low probability of tail-area violations and confirm the presence of a highly stable and well-controlled manufacturing process. The obtained capability indices provide a quantitative and mathematically grounded measure of manufacturing risk, enabling probabilistic interpretation of compliance rather than binary pass–fail assessment.

In contrast, suture length and needle attachment strength displayed reduced or negative capability indices, indicating statistically significant misalignment between process output distributions and specification constraints. In these cases, the estimated Cpk values mathematically confirm that common-cause variation alone is sufficient to generate nonconforming output, even in the absence of assignable special causes.

Needle attachment strength analysis revealed multimodal and bimodal distribution structures corresponding to distinct failure mechanisms. The coexistence of statistically separable populations violates the assumptions of unimodal capability modeling and signifies the presence of latent process instability. Under such conditions, global process capability indices lose interpretive validity unless preceded by failure-mode stratification and targeted statistical modeling.

For non-normal datasets, the application of distributional transformations enabled valid estimation of process capability while preserving interpretability of statistical risk metrics. This approach ensured that capability indices and derived nonconformance probabilities were computed within an analytically consistent framework.

Overall, the study demonstrates that process capability indices, when applied with appropriate distributional validation and failure-mode discrimination, provide a mathematically rigorous basis for risk-based quality assessment in medical device manufacturing. The proposed methodology supports quantitative prioritization of process improvements, enhances predictive understanding of manufacturing variability, and contributes to the integration of statistical quality engineering principles into regulatory compliance evaluation for absorbable polymer-based medical devices.

Declaration of Generative AI and AI-assisted technologies in the writing process During the preparation of this work, the authors used ChatGPT by OpenAI for language editing and polishing. After using this tool, the authors reviewed and revised the content as needed and take full responsibility for the final version of the publication.

References

[1] D. C. Montgomery, Introduction to Statistical Quality Control, 8th Edition, Wiley, New York, 2019.

[2] J. M. Juran, A. B. Godfrey, Juran's Quality Handbook: The Complete Guide to Performance Excellence, 7th Edition, McGraw-Hill, New York, 2016.

[3] V. E. Kane, "Process capability indices," Journal of Quality Technology, Vol. 50, No. 1, pp. 1–17, 2018.

[4] D. R. Bothe, Measuring Process Capability, McGraw-Hill, New York, 2017.

[5] R. C. H. Cheng, M. A. Stephens, "Non-normal process capability indices and transformations," Quality and Reliability Engineering International, Vol. 35, No. 2, pp. 405–421, 2019.

[6] M. Sokovic, D. Pavletic, K. K. Pipan, "Quality improvement methodologies in medical device manufacturing," International Journal of Quality & Reliability Management, Vol. 35, No. 6, pp. 1292–1311, 2018.

[7] J. C. Middleton, A. J. Tipton, "Synthetic biodegradable polymers as orthopedic devices," Biomaterials, Vol. 21, No. 23, pp. 2335–2346, 2000.

[8] M. A. Woodruff, D. W. Hutmacher, "The return of a forgotten polymer— Polycaprolactone in the 21st century," Progress in Polymer Science, Vol. 35, No. 10, pp. 1217–1256, 2010.

[9] J. Santos, R. Rebelo, F. J. G. Silva, "Failure mode analysis in medical device assembly processes," Procedia Manufacturing, Vol. 51, pp. 1093–1100, 2020.

[10] Automotive Industry Action Group (AIAG), Statistical Process Control (SPC) Manual, 3rd Edition, AIAG, Southfield, MI, 2022.

[11] N. Otkhozoria, V. Otkhozoria, Sh. Khorava. (2022). Search for an extremum using the steepest descent method under the conditions of experimental errors. World Science, (2(74). https://doi.org/10.31435/rsglobal_ws/28022022/7785

[12] D. Hoyle, ISO 13485:2016 – A Practical Guide, BSI Standards Limited, London, 2017.

[13] T. Beshidze, N. Otkhozoria, "Physical properties of biodegradable and biologically compatible copolymers after implantation until complete resorption," Foundations and Trends in Modern Learning, No. 2, 2023.