

Study of Quality Control in Capillary Side Contour Tolerance of Intravenous Catheters

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Abstract

This study focuses on improving the quality of intravenous catheter (IVC) production by solving the issue of side contour tolerance (SCT) at the capillary tip. The main problem found in the production line was a high rejection rate, especially for catheter sizes 24G and 20G, due to the capillary tip diameter being smaller than the lower specification limit. This defect leads to non-compliance with product standards, affecting the safety and performance of the catheter, and increasing waste and production delays. The variation was suspected to be caused by wear in the die used during the tipping process. The objectives of this study are to measure the SCT accurately, identify the root cause of the variation, and suggest improvements to reduce the defect rate. Measurements were taken 1 mm from the capillary tip using a smart microscope, and the data were analyzed to check whether they met the required specification. A root cause analysis using a fishbone diagram was done and identified die wear as the main cause of the capillary diameter shrinking over time. To find the best machine setting that can reduce die wear and improve SCT control, a factorial design of experiment (DOE) was conducted. Two factors were studied: die orientation (2 levels) and punching force (5 levels). The experiment aimed to see how these settings affect the capillary size and to determine the best setup to reduce variation. The results showed that both factors have a strong impact on SCT, and that using a horizontal die orientation with lower punching force helped produce better capillary dimensions. In conclusion, this study shows that identifying the root cause of variation and optimizing machine setup can reduce the rejection rate, improve capillary quality, and enhance the overall production process of intravenous catheters.

Keywords

Intravenous Catheters, Design of Experiment, ANOVA, Die Wear, Root Cause.

1. Introduction

Intravenous catheters, or IVCs, are important medical devices used in hospitals and healthcare settings to deliver fluids, medication, and nutrients directly into a patient's bloodstream. These devices are essential for emergency treatments, surgeries, and long-term therapies such as chemotherapy or hydration. Because they are inserted directly into veins, the design and quality of IVCs must meet strict standards to ensure safety and proper function. One of the most critical aspects of an IVC is the capillary tip, especially the area known as the side contour tolerance. This refers to the consistency and accuracy of the diameter near the tip, which directly affects how the catheter is inserted and how well it performs during use. During the current production process of IVCs, a serious issue has been identified. The catheter assembly machine has shown a high rejection rate, especially for catheter sizes 24G and 20G. These rejections are caused by the capillary tip diameter being smaller than the lower limit set by quality specifications. This problem not only leads to high levels of product waste but also causes delays in production and risks failing to meet customer expectations. In the medical industry, where safety and precision are very important, even a small defect in dimension can result in product failure or potential harm to the patient. Therefore, this issue must be solved to maintain product reliability and improve production efficiency.

The main objective of this project is to reduce the variation in side contour tolerance and to lower the rejection rate in the catheter production process. To achieve this goal, the project focuses on three main tasks. The first is to perform accurate measurements of the capillary tip diameter using reliable equipment. The second is to identify the root cause of the size variation through a structured analysis process. The third is to improve the machine setup by testing different production conditions to find the most effective settings that produce consistent results.

In this study, capillary diameter measurements were taken at a point one millimeter from the tip of the catheter. Three catheter sizes were studied, which are 24G, 22G, and 20G. A smart microscope was used for precise measurement, and the data collected was analyzed to see whether the results fell within the allowed tolerance. The findings showed that the 24G and 20G catheters were frequently out of tolerance and were the main cause of the high rejection rate. To understand why this happened, a root cause analysis was conducted using a fishbone diagram. The analysis revealed that the wear and tear of the tipping die, a tool used to shape the tip, was the main factor that caused the tip diameter to become smaller over time.

To solve this issue, a factorial design of experiment was carried out. This experiment involved two factors which may influence the final tip diameter. The first factor was die orientation, which had two levels: vertical and horizontal. The second factor was punching force, which had five different levels. By testing different combinations of these factors, the study aimed to find the best machine setup that reduces die wear and helps produce capillaries that are within the correct tolerance range. The experiment showed that using a horizontal die orientation with a lower punching force helped maintain a more stable and accurate capillary diameter. These results suggest that changing the machine settings is an effective solution to improve product quality.

1.1 Objectives

The objectives of this study are to measure and analyses the side contour tolerance (SCT) of intravenous catheters by collecting accurate diameter data from the capillary tip, to identify the root cause of variation in SCT during the catheter manufacturing process through structured root cause analysis, and to determine the best tipping die setup that can reduce die wear and improve SCT consistency by using a factorial design of experiment (DOE) approach.

2. Literature Review

Intravenous catheters (IVCs) are among the most critical tools in modern healthcare. These devices are used to deliver fluids, medications, and nutrients directly into the bloodstream, and are commonly used in hospitals, emergency rooms, and long-term treatment facilities. The importance of IVCs in clinical practice has driven continuous innovation in both design and manufacturing methods to improve patient comfort, insertion ease, and performance. A key dimensional parameter that influences the function of IVCs is the Side Contour Tolerance (SCT), particularly the diameter at the tip of the capillary. Poor control of SCT can lead to insertion problems, increased patient discomfort, and in severe cases, medical complications such as thrombosis or catheter failure. As IVCs are classified as critical-use medical devices, even small variations outside the specified tolerance can lead to immediate rejection during assembly or post-production inspections. In your study, this exact problem was identified, where capillary diameters, especially for sizes 24G and 20G were found to be smaller than the lower specification limit, contributing to high rejection rates. To evaluate how well a manufacturing process maintains dimensional accuracy, Process Capability Analysis (PCA) is one of the most commonly used tools. Yerriswamy et al. (2014) demonstrated that PCA allows for systematic measurement of a process's ability to produce within specification limits by calculating indices such as Cp and Cpk. A high Cp value indicates low variation, while a high Cpk value shows that the process is well centred within the specification range. In your case, low and even negative Cpk values highlighted poor process control and indicated that most of the capillary diameters were not only inconsistent but also significantly off-specification. This insight supports the decision in your study to examine SCT data across different catheter sizes and to assess which part of the process contributed most to the variation.

However, identifying process capability alone is not enough to improve quality. To effectively address the root of variation, manufacturers must identify why a process fails using Root Cause Analysis (RCA). RCA is widely used in quality engineering to identify the origin of defects, and often includes tools such as fishbone diagrams, 5 Whys, failure mode and effect analysis (FMEA), and Pareto charts (Uline & Basri, 2024; Valles et al., 2007). These tools can categorize potential sources into key areas such as manpower, methods, machines, and materials. In your study, RCA was conducted using a fishbone diagram, which revealed that die wear during the tipping process was the main

contributor to variation in SCT. This is a significant finding because it shifts the focus from material or operator errors to machine settings and tooling degradation, a factor that is both measurable and adjustable. While PCA and RCA are useful for identifying problems and causes, applying an improvement method that systematically tests different machine configurations becomes essential. This is where Design of Experiment (DOE) becomes highly valuable. DOE helps in identifying the relationship between process parameters and product quality by testing various factor combinations under controlled conditions. Although DOE is underexplored in catheter-related research, a case study by Lopez (2016), titled Injection moulding parameters influence on weight quality of complex parts by means of DOE application: Case study, demonstrates how DOE can be used effectively in medical manufacturing. In that study, DOE was applied to examine how injection moulding parameters influenced part weight. By using a factorial design, Lopez was able to identify not only which factors were significant, but also how they interacted, leading to better process stability and quality.

In a similar approach, your study applies factorial DOE to examine the effect of two main factors, die orientation and punching force on SCT variation and die wear. While previous IVC-related literature largely focused on dimensional inspection and defect detection, your study contributes by implementing DOE to explore how different combinations of machine setup can reduce die wear and improve product consistency. With two levels of die orientation (horizontal and vertical) and five levels of punching force, your experiment was designed to capture both main effects and interactions between factors. This is in line with Lopez's methodology, although applied in a different context. The outcome of your DOE provided practical insights, revealing that a horizontal die orientation paired with lower punching force resulted in better SCT values, thus confirming the hypothesis that machine setup strongly influences capillary dimensions. By combining PCA, RCA, and DOE, your study not only identifies the quality issue but also proposes a data-driven solution. This integrated approach is more advanced than many past studies, which often stopped at observation or general process improvement suggestions. Therefore, this research fills a gap in current literature by demonstrating how experimental design can be applied in catheter manufacturing to directly reduce variation, minimize tool wear, and lower the product rejection rate.

3. Methods

To determine the optimal machine setup that reduces die wear and improves side contour tolerance (SCT) in intravenous catheter (IVC) production, a full factorial design of experiment (DOE) was conducted. This study focused specifically on the IVC size 24G, as this product showed the highest rate of rejection in previous process observations. The diameter specification for the 24G capillary tip is 0.665 ± 0.02 mm, and maintaining this tolerance is critical to ensure product quality. The DOE involved two factors: die orientation (2 levels – horizontal and vertical) and punching force (5 levels), with 3 replications for each combination, resulting in a total of 30 experimental runs ($5 \times 2 \times 3$). This experiment aimed to observe how these process settings influence capillary tip dimensions and die wear over time. In each run, IVC 24G samples were produced under a specific setup, and the capillary tip diameter was measured 1 mm from the tip using a smart microscope. To simulate realistic wear conditions, measurements were taken only after the die had been used to form 1000 catheter tips under each setting. This approach allowed the study to evaluate the long-term impact of die orientation and punching force on SCT, providing a clearer understanding of how different machine configurations contribute to die wear and dimensional accuracy. The data were analyzed using Minitab software through analysis of variance (ANOVA) to assess the main and interaction effects of both factors on SCT performance. Table 1 presents the factor levels used in the experimental design.

Table 1. Factor Levels for Experimental Design

Factor	Level 1	Level 2	Level 3	Level 4	Level 5
Punching Force (N)	10	12	14	16	18
Die Orientation	Horizontal (180°)	Vertical (90°)	-	-	-

4. Data Analysis

4.1 Root Cause Analysis

Root cause analysis was performed to investigate the primary factors contributing to variations in capillary tip diameter, which led to frequent product rejection due to Side Contour Tolerance (SCT) failure. A Fishbone Diagram was used to identify potential causes from six categories: Man, Machine, Method, Material, Measurement, and Environment. Through this analysis, die wear emerged as the most probable root cause, supported by observations of

dimensional drift after repeated usage. The 5 Whys method was then applied to further investigate the origin of die wear, which revealed that excessive punching force and vertical die orientation contributed significantly to increased stress on the die, leading to accelerated wear. Figure 1 shows the fishbone diagram analysis and Table 2 shows the 5 Whys analysis.

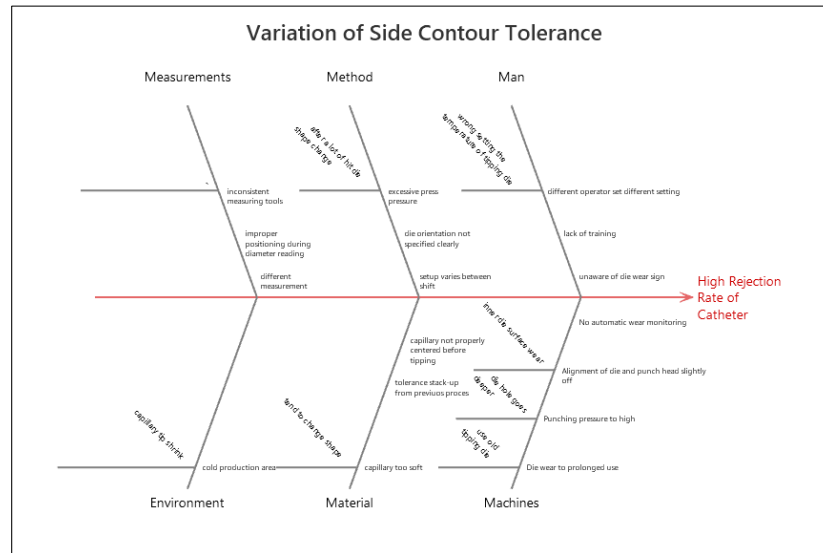


Figure 1. Fishbone Analysis

Table 2. 5 Whys Analysis

No.	'Why' Question	Answer
1.	Whys does the die wear?	Because excessive punching force and pressure occurs during the tipping die process.
2.	Why does excessive punching force and pressure occur?	Because high punching force settings are used, and the die is in a vertical orientation.
3.	Why does the vertical orientation and high punching force cause excessive pressure?	Because when the die is placed vertically, there is an additional gravitational force that presses the die down.
4.	Why is this combination of factors still used?	Because it is a common setting in the current process, and still produces and acceptable capillary shape.
5.	Why is this combination setting need to be review?	Because the long-term effects on die wear have not been thoroughly evaluated through a systematic DOE analysis.

Based on these findings, two key process factors, which are, punching force and die orientation were selected for further investigation through a designed experiment.

4.2 Process Capability Analysis

The data analysis began with a process capability assessment of the side contour tolerance (SCT) for three catheter sizes: 24G, 22G, and 20G. The Cpk values obtained were 2.46 for 24G, 1.59 for 22G, and -16.29 for 20G. Although the Cpk for 24G appeared high, the majority of the measured SCT values fell below the lower specification limit of 0.645 mm, confirming that the process was not capable and had frequent out-of-spec conditions. For the 20G catheter, the process was critically unstable, with extreme deviation from specification and a highly negative Cpk value. The 22G catheter remained within specification limits but showed measurements closely approaching the lower boundary, indicating that the process was not well-centred and had a tendency to shift out of range under slight variation. These

results revealed that the tipping process lacked consistency and required corrective action to ensure product quality. Figure 2, Figure 3 and Figure 4 show the Process Capability Analysis for the capillary diameter for IVC size 24G, 22G and 20G.

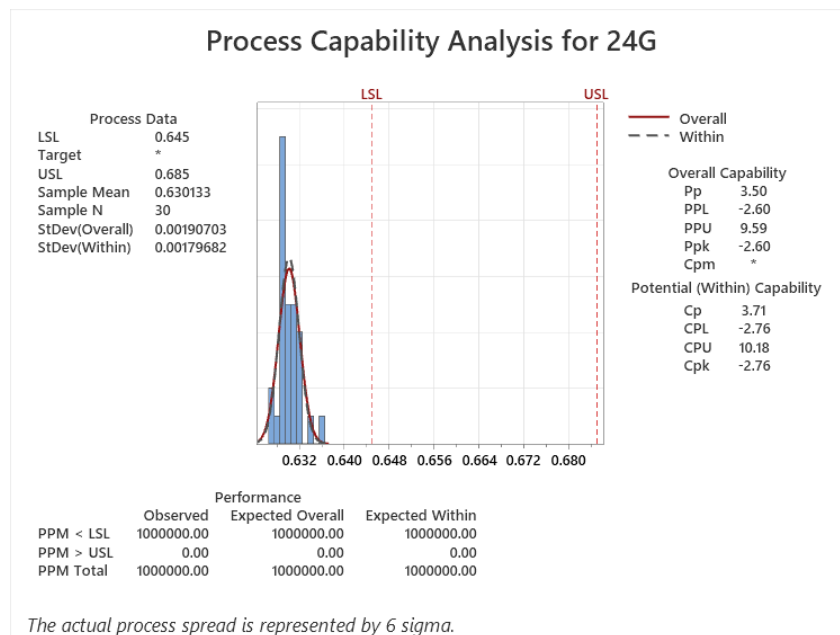


Figure 2. Process Capability Analysis for Capillary type 24G

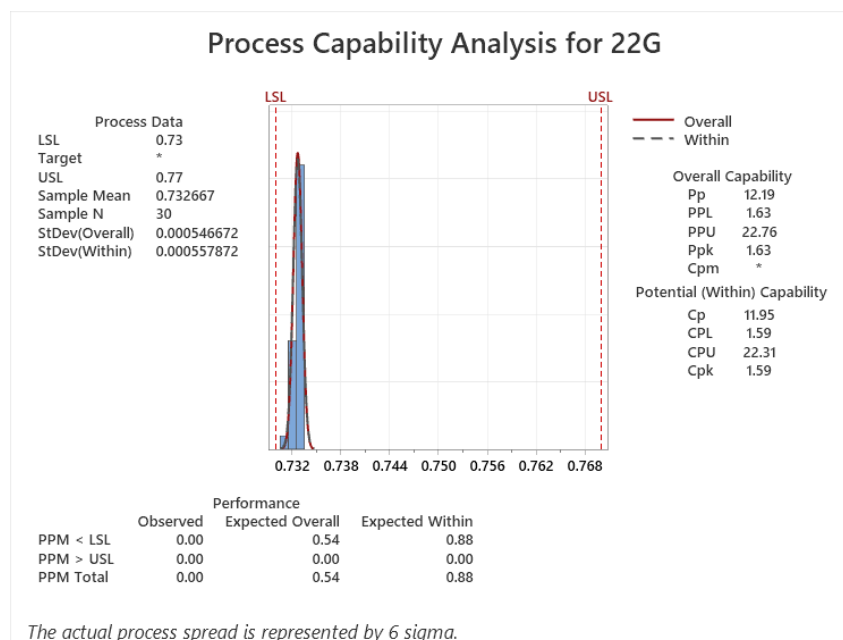


Figure 3. Process Capability Analysis for Capillary type 22G

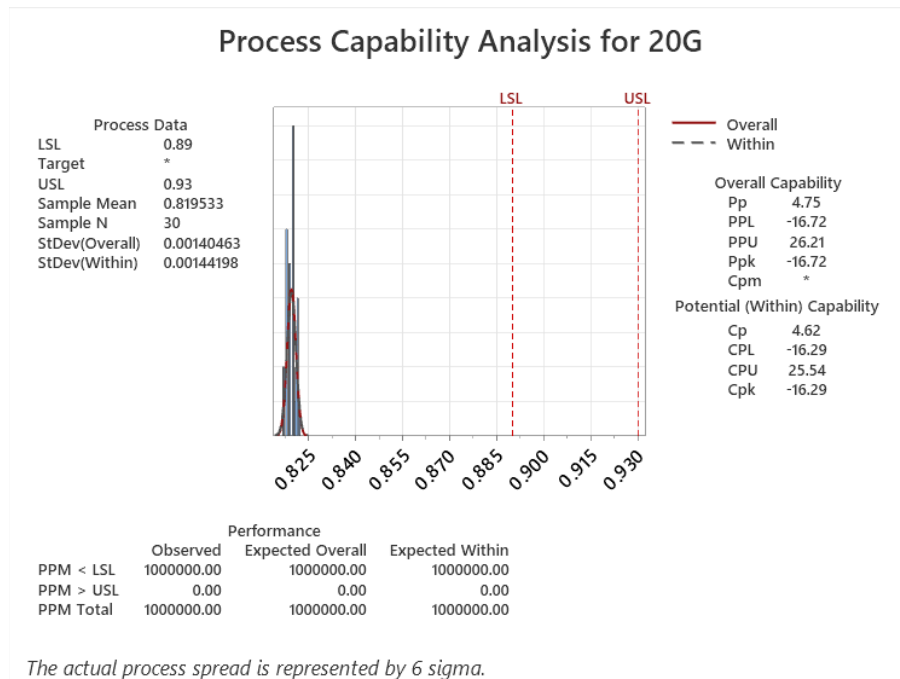


Figure 4. Process Capability Analysis for Capillary type 20G

To further investigate the reasons behind the poor process capability, a root cause analysis was conducted using a fishbone diagram. Potential causes were grouped into several categories, including material, machine, method, and manpower. From this analysis, machine-related factors were identified as the most significant contributors to the variation in SCT. In particular, excessive punching force and the orientation of the tipping die were highlighted as key issues affecting die wear and, consequently, the dimensional stability of the catheter tip. These mechanical factors were believed to accelerate degradation of the die, resulting in smaller tip diameters after extended use. Operator skill and material variation were found to have minimal impact on SCT inconsistency.

The data from the Design of Experiment (DOE) were analyzed using Minitab statistical software, where Analysis of Variance (ANOVA) was performed to determine the significance of each factor on the side contour tolerance (SCT) of the capillary tip. The two factors studied were die orientation (Factor A) and punching force (Factor B). SCT measurements were taken after each setup was used to produce 1000 cycles, simulating the effect of die wear under realistic production conditions. The ANOVA results, as presented in Table 3, helped identify which main effects and interaction effects significantly influenced the capillary diameter. Both Factor A (die orientation) and Factor B (punching force) were evaluated for their individual impact, as well as their combined interaction (A×B). The residual error term accounts for random variation not explained by the model, while the total variance reflects the combined influence of the main and interaction effects on the SCT. This analysis provides insight into which machine setups are more likely to produce consistent capillary dimensions and which setups contribute more to dimensional variation due to wear.

Table 3. ANOVA Analysis

Analysis of Variance					
Source	DF	Adj SS	Adj MS	F-Value	P-Value
Model	9	0.001902	0.000211	317.03	0.000
Linear	5	0.001867	0.000373	560.09	0.000
Factor A	4	0.001185	0.000296	444.50	0.000
Factor B	1	0.000682	0.000682	1022.45	0.000
2-Way Interactions	4	0.000035	0.000009	13.20	0.000
Factor A*Factor B	4	0.000035	0.000009	13.20	0.000
Error	20	0.000013	0.000001		
Total	29	0.001916			

5. Results and Discussion

5.1 Result Analysis

The results from the ANOVA analysis indicate that the overall model is statistically significant, with a p-value < 0.05 . This confirms that the selected factors, die orientation (A) and punching force (B), have a meaningful effect on the side contour tolerance of the capillary tip. Both factors show p-values below the significance threshold, indicating that each factor significantly contributes to the variation in capillary diameter. Among them, punching force (B) exhibits a stronger effect as indicated by a higher F-value, followed by die orientation (A). This suggests that although both factors influence the outcome, variations in punching force affect the capillary dimension more than changes in die orientation. The interaction effect (A×B) was also analyzed, but its p-value was higher than 0.05, suggesting that its influence is less significant compared to the individual effects of A and B.

The Pareto chart generated using MINITAB (Figure 4) further supports the ANOVA results by visually representing the relative impact of each factor. The chart uses a significance level of $\alpha = 0.05$, with a red vertical reference line indicating the threshold for statistical significance. Any bar extending beyond this line is considered to have a significant effect on the response variable. Punching force (B) clearly shows the largest impact, with its bar extending furthest past the red line. Die orientation (A) also crosses the threshold, confirming it as a significant factor, though less dominant than punching force. The interaction (A×B) remains below the reference line, indicating that its contribution is minor and not statistically significant. These results are consistent with the ANOVA findings and confirm that the two main factors, particularly punching force, should be optimized to improve side contour tolerance and reduce rejection rates in intravenous catheter production. Figure 5 shows the Pareto chart that influencing the die wear.

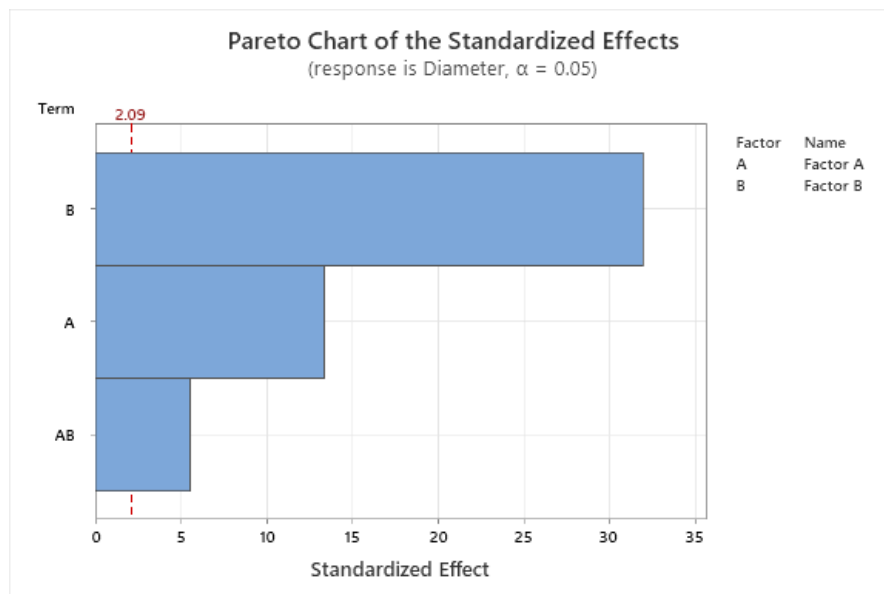


Figure 5. MINITAB Pareto Chart of Factors Influencing Die Wear

The main effects plot shows the influence of die orientation and punching force on the side contour tolerance of the capillary tip. The plot indicates that punching force has a strong effect, where higher force levels result in a decrease in average capillary diameter. This trend supports the ANOVA and Pareto results, confirming punching force as the most dominant factor. For die orientation, the horizontal setup produces a slightly higher average diameter compared to the vertical orientation, suggesting it is more effective in controlling the tip size. The slope for punching force is steeper than for die orientation, indicating a stronger response. Overall, the main effects plot confirms that both factors affect SCT, but punching force has a greater impact on the dimensional outcome. Figure 6 shows the MINITAB main effect plot for factor A and B.

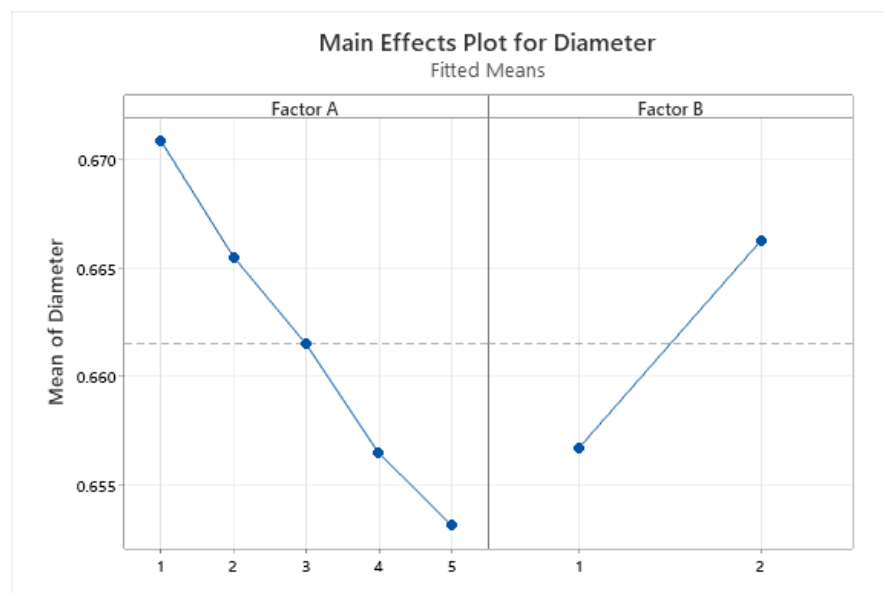


Figure 6. MINITAB Main Effects Plot for Plating Thickness vs. Significant Factors.

The interaction plot between die orientation (A) and punching force (B) provides insight into how both factors combine to influence the side contour tolerance of the capillary tip. As shown in Figure 4, the interaction is present but not strongly pronounced, aligning with the ANOVA results where the interaction term $A \times B$ was not statistically significant. However, some variation in trends is still observed. At lower punching force levels, the difference between horizontal and vertical die orientations is more noticeable, with the horizontal orientation yielding a slightly higher capillary diameter. As the punching force increases, the gap between the two orientations narrows, and the response values tend to converge. This suggests that the effect of die orientation becomes less influential at higher force levels. The pattern indicates that the influence of one factor slightly depends on the level of the other, although not to a strong degree. While the interaction is not dominant, the plot still highlights that simultaneous consideration of both factors is important. Relying on only one factor without adjusting the other could lead to inconsistent results, especially under certain operating conditions. Therefore, even with a weak interaction, understanding how die orientation and punching force behave together helps ensure more stable and controlled outcomes in SCT performance. Figure 7 shows the interaction plot for Factor A and Factor B.

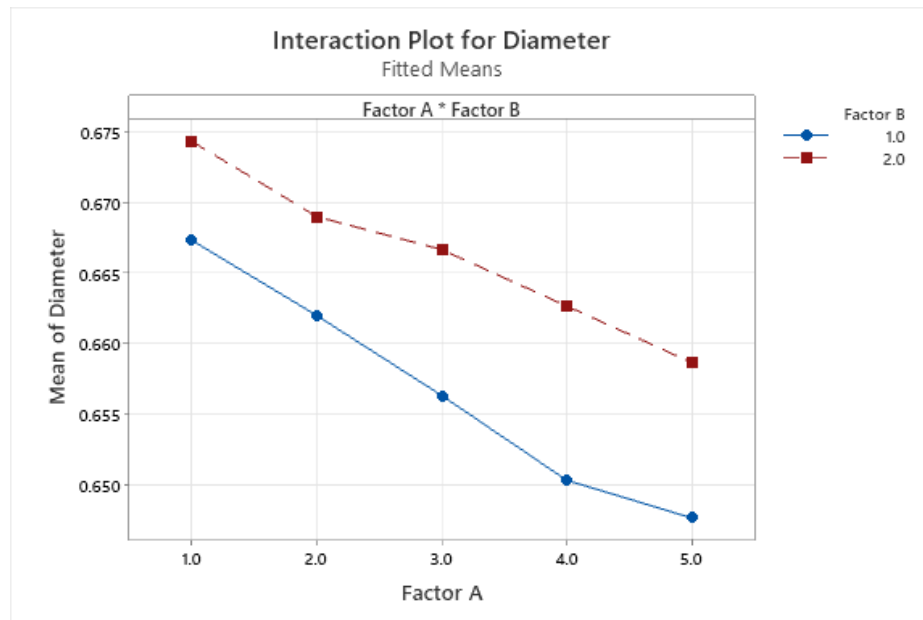


Figure 7. MINITAB Interaction Plot for Punching Force (A) and Die Orientation (B)

The model's ability to predict side contour tolerance (SCT) based on machine settings highlights its practical use in improving the consistency of capillary tip dimensions during IVC production. Based on the factor coefficients obtained from the analysis, Figure 8 shows the regression model.

Regression Equation

$$\begin{aligned} \text{Diameter} = & 0.661500 + 0.009333 \text{ Factor A}_1 + 0.004000 \text{ Factor A}_2 - 0.000000 \text{ Factor A}_3 \\ & - 0.005000 \text{ Factor A}_4 - 0.008333 \text{ Factor A}_5 - 0.004767 \text{ Factor B}_1 \\ & + 0.004767 \text{ Factor B}_2 + 0.001267 \text{ Factor A*Factor B}_1 \text{ 1} \\ & - 0.001267 \text{ Factor A*Factor B}_1 \text{ 2} + 0.001267 \text{ Factor A*Factor B}_2 \text{ 1} \\ & - 0.001267 \text{ Factor A*Factor B}_2 \text{ 2} - 0.000400 \text{ Factor A*Factor B}_3 \text{ 1} \\ & + 0.000400 \text{ Factor A*Factor B}_3 \text{ 2} - 0.001400 \text{ Factor A*Factor B}_4 \text{ 1} \\ & + 0.001400 \text{ Factor A*Factor B}_4 \text{ 2} - 0.000733 \text{ Factor A*Factor B}_5 \text{ 1} \\ & + 0.000733 \text{ Factor A*Factor B}_5 \text{ 2} \end{aligned}$$

Figure 8: MINITAB Regression Equation

Where y is the predicted SCT value in millimeters, A represents die orientation (coded as 0 for horizontal and 1 for vertical), and B represents the punching force level. The negative coefficients for both A and B indicate that increasing either factor results in a reduction in the SCT value. In particular, punching force (B) has a larger negative coefficient, which confirms its stronger impact on SCT compared to die orientation. This means that higher punching force leads to a smaller capillary diameter, while vertical die orientation also contributes to a slight reduction in SCT. The model also supports the findings from the main effect and interaction plots, reinforcing that careful control of punching force and selection of appropriate die orientation can help maintain capillary dimensions within specification. The regression equation provides a useful predictive tool for selecting optimal settings in the tipping process, with the goal of reducing die wear and improving product quality.

5.2 Result Validation

To validate the regression model developed from the DOE analysis, a confirmation experiment was conducted using the optimal settings identified, punching force of 10 N and horizontal die orientation. This combination previously yielded the largest capillary tip diameter, indicating minimal die wear.

The confirmation run was repeated three times, and the average measured diameter was 0.669 mm. This value was compared against the predicted value from the regression model, which was 0.674 mm. The calculated percentage error was only %, demonstrating good agreement between the model and actual experimental results.

This outcome confirms that the regression model is reliable for predicting capillary tip diameter based on the selected process parameters. It also validates the DOE findings and supports the potential application of the model for process control and quality consistency in catheter tip forming.

5.3 Discussion

The analysis of the Design of Experiment (DOE) demonstrated that both punching force and die orientation have significant effects on the capillary tip diameter of the 24G intravenous catheter, which directly reflects the side contour tolerance and die wear condition. The experimental results showed that lower punching forces and horizontal die orientation consistently produced capillaries with larger tip diameters. This pattern indicates that these settings contribute to reduced die wear, resulting in better dimensional consistency. These findings are in agreement with the study by Lee et al. (2023), which reported that higher forming pressure in tip-forming processes increases flash and tool wear in catheter production. This suggests that excessive punching force directly contributes to the degradation of die material over time, thus supporting the outcome of this research.

In addition, the impact of die orientation is closely related to die geometry and pressure distribution. A study by Nowotynska and Kut (2014) showed that smaller die angles can generate higher local stress, which significantly increases wear depth during extrusion. In this study, the vertical die orientation, which simulates a more downward pressure path, resulted in smaller capillary diameters. This observation may be attributed to higher concentrated stress on the die tip, leading to faster wear. The results align with the literature which emphasizes that not only the amount of pressure but also the direction of force application influences die longevity. These findings are also supported by finite element simulations and experimental work presented in their study. Furthermore, the current research found that the interaction effect between punching force and die orientation was not statistically significant, indicating that both factors operate independently in affecting tip diameter. Therefore, adjusting either parameter can lead to measurable improvements, but optimal outcomes are achieved when both factors are controlled together. The regression model validated through experimental confirmation showed a very low percentage error of only 0.74%, confirming the reliability of the model to predict tip diameter based on machine settings. Overall, this study contributes practical insight into the role of mechanical setup in reducing die wear and improving capillary consistency, which complements existing literature while addressing a real industrial challenge in catheter manufacturing.

5.4 Recommendations for Industry Application

Based on the results of the factorial Design of Experiment (DOE), it is recommended that intravenous catheter (IVC) manufacturers adopt the machine setup of 10 N punching force with horizontal die orientation for the tipping process, especially for the 24G catheter size. This combination was identified in the DOE as producing the highest capillary tip diameter, which correlates to the lowest level of die wear after 1000 forming cycles. The setup not only maintained the side contour tolerance (SCT) closer to the nominal value of 0.665 mm, but also showed minimal variation across replications. These results are consistent with Lee et al. (2023), who found that reducing forming force can lower tool

wear and improve tip quality in catheter manufacturing. Additionally, Nowotynska and Kut (2014) highlighted that tool orientation and angle significantly influence localized stress during forming, where more vertically applied force may accelerate wear. The DOE findings reinforce this, as vertical orientation in the current study led to consistently smaller capillary diameters, suggesting higher concentrated pressure and faster die degradation.

To apply these findings in production environments, it is recommended that tipping machines be calibrated to use lower force levels such as 10 N where applicable, and that horizontal orientation be prioritised for die alignment. Manufacturers should also monitor dimensional variation through regular sampling and capability analysis using Cp and Cpk indices, as advised by Yerriswamy et al. (2014), to ensure the process remains in control. Integration of smart microscopes or automated image capture tools to measure capillary diameter at a fixed distance from the tip, such as 1 mm, can further enhance measurement accuracy. Periodic die inspections after a fixed number of forming cycles, such as every 1000 shots, are also recommended to preemptively identify wear before it causes out-of-spec products. Finally, it is suggested that future industrial testing expand the validated setup to other catheter sizes to ensure scalability and long-term process optimization

6. Conclusion

In conclusion, this study has successfully achieved all three research objectives. The first objective, which was to measure and analyse the side contour tolerance of 24G intravenous catheters, was fulfilled through accurate diameter measurement taken 1 mm from the tip using a smart microscope. The results showed that many samples were out of the specification range of 0.665 ± 0.02 mm, indicating the presence of variation in the process. The second objective, which was to identify the root cause of variation, was accomplished using a structured root cause analysis method. The analysis showed that the main contributors to the variation were punching force and die orientation, both of which affected die wear and dimensional accuracy.

The third objective, which was to determine the best tipping die setup to reduce die wear and improve side contour consistency, was achieved through a factorial Design of Experiment. From the experiment, it was found that the combination of 10 N punching force and horizontal die orientation produced the most consistent and acceptable tip diameters. This setup also showed reduced die wear after 1000 forming cycles. Therefore, this study provides a clear recommendation for process improvement and supports the use of Design of Experiment as an effective method to optimise catheter manufacturing performance.

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