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Quality Control Analysis of Products Using the Six Sigma Method: A Case Study at PT. XYZ

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ABSTRACT

The A.V. Fistula is a critical medical device required to comply with stringent quality standards under ISO 13485, making systematic quality control essential. This study aims to analyze and improve A.V. Fistula product quality at PT. XYZ through the Six Sigma DMAIC (Define, Measure, Analyze, Improve, Control) methodology. Production data recorded from April 2023 to March 2024 revealed 148,682 defective units from a total of 49,813,422 units produced, with four primary defect types identified: Scratch, Cannula Loose, Foreign Particle, and Bent Needle Tip. Pareto analysis identified Scratch as the dominant defect category (63,580 units; 42.8% of total defects). Fishbone diagram and FMEA analyses identified the principal root causes: tube dimensions outside tolerance (RPN = 180), improper storage of sharp materials (RPN = 160), operator handling errors (RPN = 140), and raw material contamination (RPN = 128). Corrective measures at the Improve stage included operator retraining, SOP revision, adoption of precision measurement tools, and automated visual inspection systems. Post-improvement monitoring data (January-March 2025) demonstrated a reduction in the average defect rate from 0.31% to 0.20% and an increase in the process sigma level from 4.67 to 4.80. These results confirm that the Six Sigma DMAIC methodology effectively reduces process variability, enhances production stability, and advances the company toward a zero-defect objective. This research provides a replicable framework for continuous improvement in the medical device manufacturing industry.

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INTRODUCTION

Globalization and rapid technological advancement have brought profound changes across various industrial sectors, including manufacturing in Indonesia. Companies are under continuous pressure to improve operational efficiency and product quality to survive in increasingly competitive markets (Hasibuan & Larisang, 2024). Product quality has become a decisive factor in sustaining competitiveness, minimizing customer dissatisfaction, and fulfilling consumer expectations (Purnama & Mutaqin, 2023).

In the production process, the Quality Assurance (QA) function is indispensable for maintaining standards and ensuring conformity. QA employee performance directly influences production outcomes and overall productivity (Rini, 2022). Prior studies confirm that quality improvement can be achieved through process optimization, machine standardization, production rescheduling, and systematic operator training (Ridho et al., 2022).

One proven approach to reducing defective product output is Six Sigma, implemented through the DMAIC (*Define, Measure, Analyze, Improve, Control*) cycle. This methodology provides a structured framework for identifying root causes, implementing data-driven improvements, and ensuring sustained quality compliance with international standards (Hairiyah & Amalia, 2020; Gaspersz, 2007).

PT. XYZ is a company producing various medical equipment including syringes, transfusion bags, and A.V. Fistula. In the medical device industry, adherence to international quality standards such as ISO 13485 is critical because it directly relates to patient safety; thus, the principle of zero defect must be applied (Budiarto, 2021). Preliminary data indicate that A.V. Fistula production from April 2023 to March 2024 reached 49,813,422 units, with 148,682 defective units, representing approximately 0.31%. This condition necessitates the implementation of Six Sigma methodology to minimize defects and enhance quality control.

Based on this background, the present study is titled "Quality Control Analysis of Products Using the Six Sigma Method: A Case Study at PT. XYZ." It is expected to contribute to improving the company's international market competitiveness and meeting ISO 13485 quality requirements.

Quality is used as a competitive tool and to provide assurance to customers. Quality is defined as the totality of the characteristics of a product that supports its ability to meet stated or specified needs (Rosyidi & Izzah, 2021). Quality control refers to activities carried out to ensure that production and operational activities are executed as planned, and that any deviations are corrected so that anticipated results are achieved (Nisa et al., 2024).

A defective product is one produced that does not meet company-established standards but may still be improved (Habib, 2022). This encompasses a range of values that cannot be associated with specific quality characteristics or specifications.Six Sigma is a method used to reduce defective product output (Ridho et al., 2022). It is defined as a continuously operating effort aimed at reducing variation, defects, and resource depletion (Setiawan, 2022).

The DMAIC method provides a way to understand problems, identify root causes, and generate solutions (Hairiyah & Amalia, 2020). It consists of five phases (Rinjani et al., 2021): (1)

Define identify problems and establish CTQ (*Critical to Quality*) frequencies; (2) Measure develop samples, test DPMO and Sigma levels, and assess process capacity; (3) Analyze determine defect causes using fishbone diagrams and FMEA; (4) Improve implement corrective actions based on prioritized root causes; (5) Control maintain improvements and prevent recurrence of primary failure causes (Purnama & Mutaqin, 2023).

METHODS

1. Research Location and Time

This research was conducted at PT. XYZ, Quality Assurance (QA) Division, from September 2024 to August 2025. Data were collected to obtain an overview of applied quality processes and efficiency. The QA Division plays an important role in ensuring received materials meet quality standards to support smooth production operations.

2. Type of Research Data

The research data comprised primary and secondary data. Primary data were obtained directly from PT. XYZ, including A.V. Fistula production quantities, defect counts, and product conditions from April 2023 to March 2024 (Nurjanah, 2021). Secondary data were obtained through documents, reports, and relevant references including production standards and prior research (Rini, 2022; Syahputri et al., 2023). Collected data include quantitative data (production and defect figures) and qualitative data (material descriptions, sample quantities, and types of detected deficiencies).

3. Population and Sample

This research used a Six Sigma approach with a population of all A.V. Fistula products manufactured from April 2023 to March 2024. Because all units were analyzed, the research sample represented the entire population, making the results comprehensively reflect process variability and production quality.

4. Data Collection Method

Data collection employed direct observation at the company, literature study, interviews, and direct documentation.

5. Data Processing Method

Data processing followed the DMAIC (Define, Measure, Analyze, Improve, Control) approach. Each phase has specific objectives and data analysis techniques to achieve continuous improvement in processes or products (Suseno & Ashari, 2022).

RESULTS

1. Define

The Define stage identifies the main problem and establishes the scope of product defects in the form of CTQ (*Critical to Quality*) as shown in Table 1.

Table 1. CTQ Potential of A.V. Fistula Product

No	Critical To Quality	Description
1	*Scratch*	Scratches or abrasions on the outer surface of the cannula caused by improper production, packaging, or handling processes.
2	*Cannula Loose*	Condition where the cannula is not firmly attached or is loose in the area where it should be secured.
3	*Foreign Particle*	Presence of foreign particles trapped in or mixed with the cannula material, either internally or externally.
4	*Bent Needle Tip*	Refers to a bent or curved needle that can occur during production processes.

Table 1 presents the CTQ for A.V. Fistula products, which includes four main defect types: Scratch, Cannula Loose, Foreign Particle, and Bent Needle Tip. These four defect types are critical quality control parameters because they directly affect product performance, safety, and reliability.

2. Measure

Determining Defect Percentage

Table 2. Defect Type Percentage

Defect Type	Total Defect	Defect %	Cumulative %
Scratch	63,580	42.8	42.8
Bent Needle Tip	40,167	27.0	69.8
Foreign Particle	27,830	18.7	88.5
Cannula Loose	17,105	11.5	100.0
Total	**148,682**	**100.0**	

Table 2 presents four main defect types found in A.V. Fistula products at PT. XYZ during April 2023 to March 2024. Scratch is the dominant defect (42.8%), followed by Bent Needle Tip (27.0%), Foreign Particle (18.7%), and Cannula Loose (11.5%).

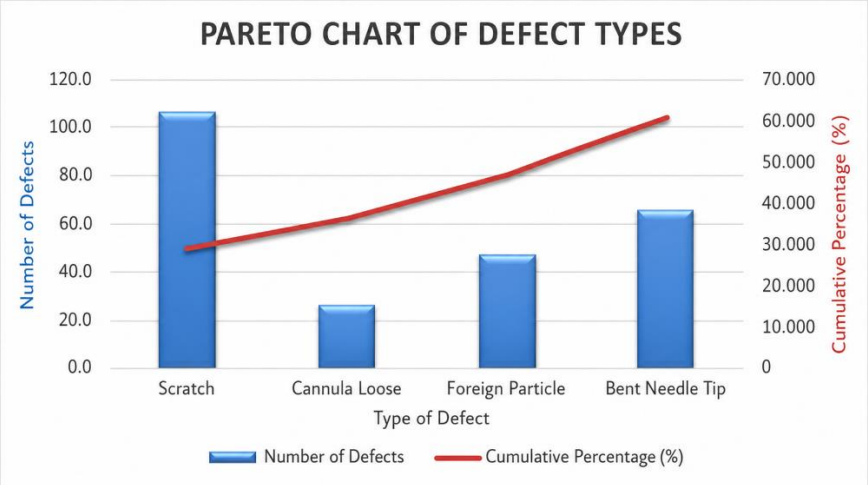

Figure 1. Pareto Diagram of Defect Types

CTQ Identification with P-Control Chart

Table 3. P-Control Chart Calculation Results

Month	P	CL	UCL	LCL
Apr-23	0.0033	0.0029	0.0163	-0.0105
May-23	0.0030	0.0029	0.0163	-0.0105
Jun-23	0.0029	0.0029	0.0163	-0.0105
Jul-23	0.0027	0.0029	0.0163	-0.0105
Aug-23	0.0024	0.0029	0.0163	-0.0105
Sep-23	0.0023	0.0029	0.0163	-0.0105
Oct-23	0.0030	0.0029	0.0163	-0.0105
Nov-23	0.0021	0.0029	0.0163	-0.0105
Dec-23	0.0030	0.0029	0.0163	-0.0105
Jan-24	0.0044	0.0029	0.0163	-0.0105
Feb-24	0.0044	0.0029	0.0163	-0.0105
Mar-24	0.0034	0.0029	0.0163	-0.0105

Table 3 presents P-control chart calculation results for monitoring the proportion of defective A.V. Fistula products from April 2023 to March 2024. The analysis shows that production is generally within statistical control as all proportion values (P) remain below the upper control limit (UCL). However, notable increases occurred in January and February 2024, signaling potential systematic deviations that may be developing.

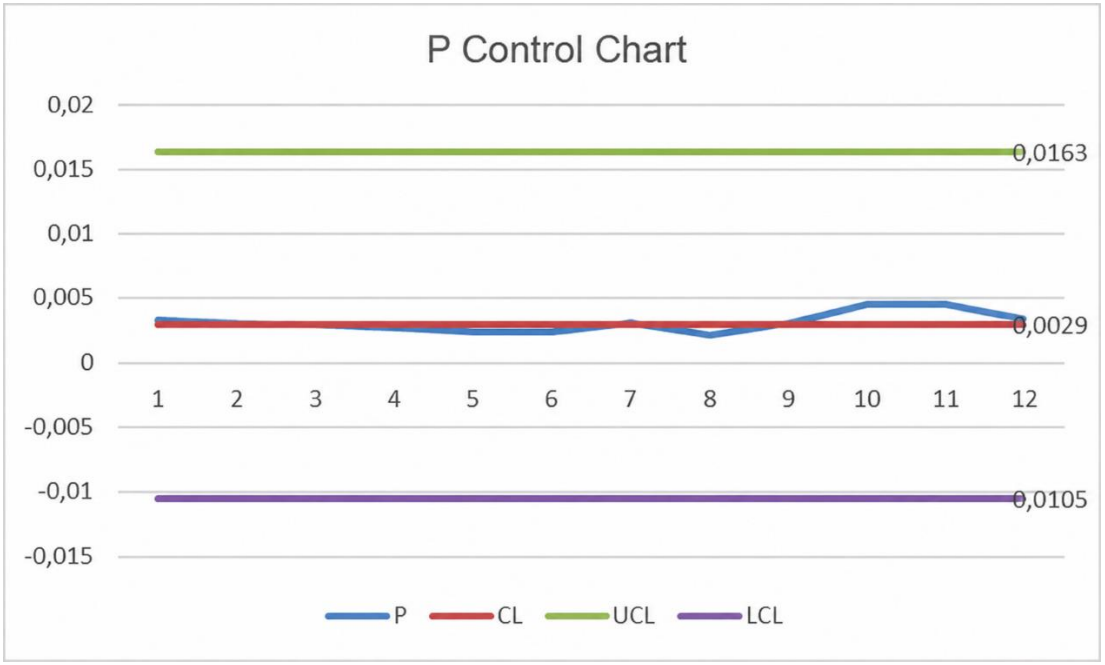

Figure 2. P-Control Chart

The chart reveals a contradiction between statistical control and process stability. Although the UCL–LCL range indicates the process is theoretically controlled, practical stability is questionable due to outlier points particularly in January and February 2024.

Calculating Six Sigma Level and DPMO

Table 4. Summary of DPMO and Sigma (σ) Values Before Improvement

Month	Production	Defects	DPU	DPMO	Sigma Level
Apr-23	4,872,134	16,165	0.0008	829.46	4.65
May-23	5,563,545	16,632	0.0007	747.36	4.68
Jun-23	5,657,746	16,180	0.0007	714.94	4.69
Jul-23	5,504,910	15,084	0.0007	685.02	4.70
Aug-23	5,438,991	13,104	0.0006	602.31	4.74
Sep-23	4,222,953	9,522	0.0006	563.70	4.76
Oct-23	4,168,785	12,491	0.0007	749.07	4.68
Nov-23	3,410,163	7,040	0.0005	516.10	4.78
Dec-23	2,911,810	9,510	0.0008	816.50	4.65
Jan-24	2,862,757	12,586	0.0011	1,099.11	4.56
Feb-24	2,571,910	11,377	0.0011	1,105.89	4.56
Mar-24	2,627,718	8,991	0.0009	855.40	4.64

Table 4 shows that although A.V. Fistula production at PT. XYZ has achieved good quality performance overall, process instability remains. The average sigma value of 4.67 indicates quality approaching world-class manufacturing standards, but not yet fully consistent.

3. Analyze

Fishbone Diagram

Fishbone diagrams were developed for each CTQ to identify root causes across four categories: man, machine, method, and material.

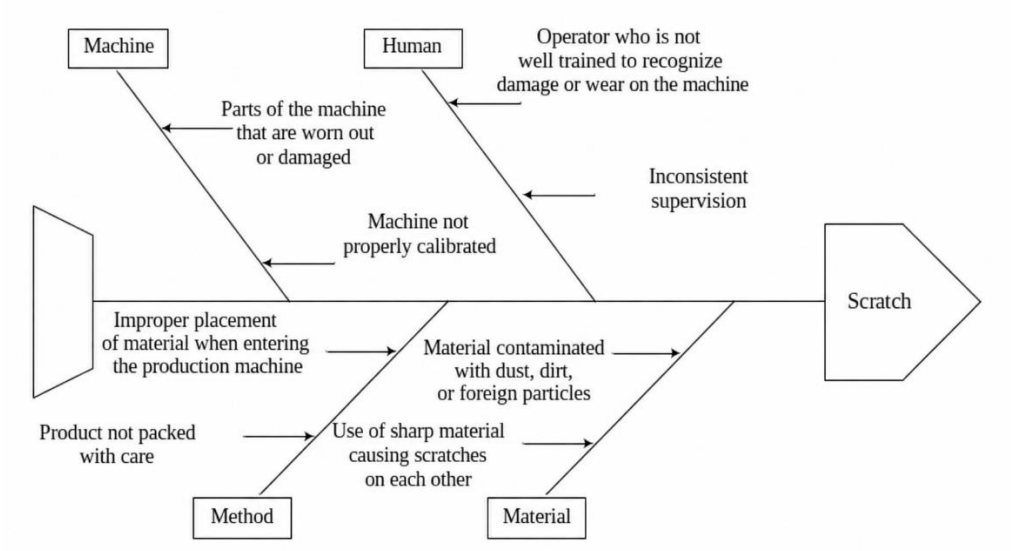

Figure 3. Fishbone Diagram Scratch

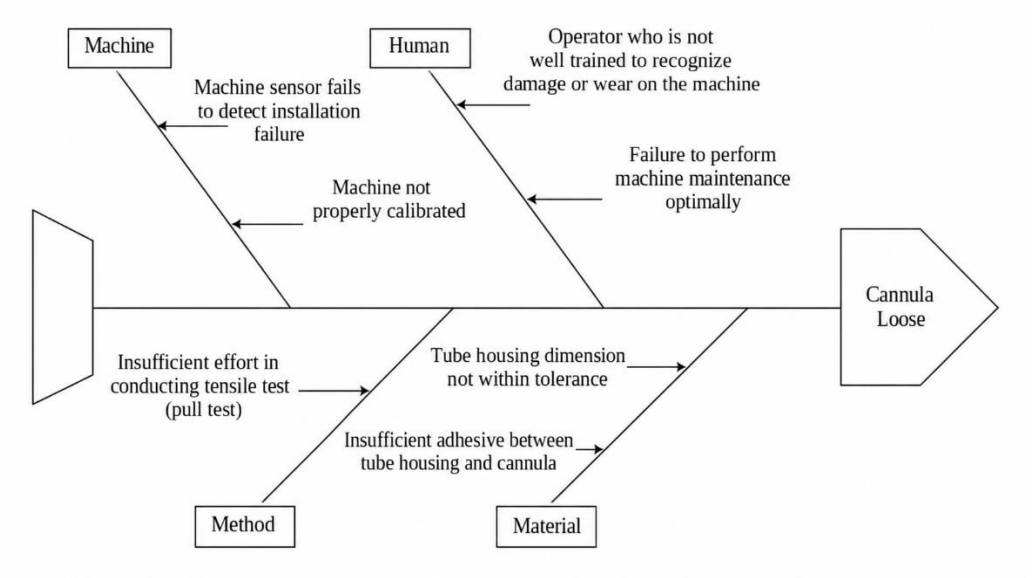

Figure 4. Fishbone Diagram — Cannula Loose

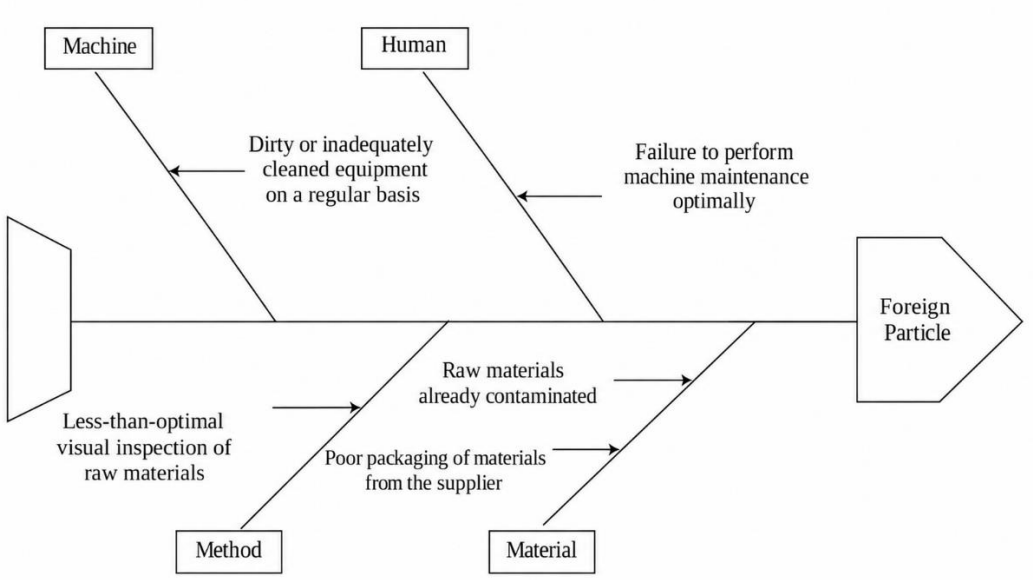

Figure 5. Fishbone Diagram Foreign Particle

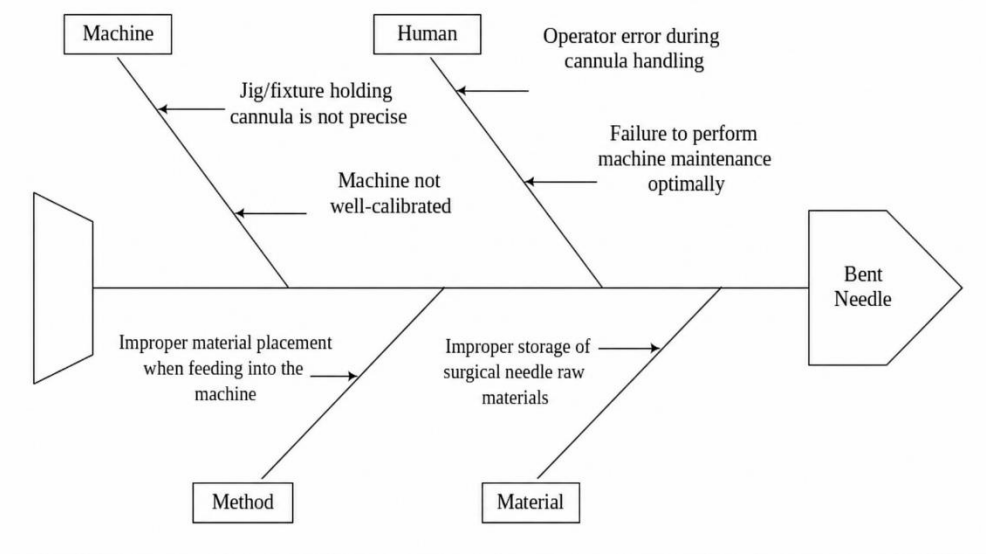

Figure 6. Fishbone Diagram Bent Needle Tip

Analysis of fishbone diagrams for all four CTQs reveals that defect root causes are not singular but result from complex interactions among human, machine, method, and material factors. For Scratch defects, causes are primarily related to improper manual handling, worn production tools, and rough packaging materials. For Cannula Loose, causes stem from assembly method accuracy and adhesive quality control. Foreign Particle defects are closely linked to poor workplace cleanliness, inconsistent machine cleaning, and insufficient incoming material inspection. Bent Needle Tip tends to be triggered by improper raw material storage and imprecise jigs.

FMEA Results

Table 5. Failure Mode and Effect Analysis (FMEA)

Defect Type	Potential Cause	S	O	D	RPN
Scratch	Worn/damaged machine parts	6	3	4	72
	Improperly calibrated machine	5	4	4	80
	Operator unaware of machine damage	6	5	5	150
	Inconsistent supervision	6	4	6	144
	Material contaminated with dust/foreign particles	5	2	3	30
	Sharp material scratches product	8	4	5	160
	Incorrect material placement into production machine	5	3	3	45
	Products not packaged carefully	4	2	4	32
Cannula Loose	Machine sensor fails to detect installation failure	7	3	4	84
	Improperly calibrated machine	6	4	4	96
	Operator insufficiently trained	7	4	5	140
	Inadequate machine maintenance	6	3	4	72
	Insufficient pull test execution	8	4	4	128
	Tube housing & cannula dimensions out of tolerance	9	4	5	180

	Non-optimal machine maintenance	7	3	3	63
	Suboptimal visual inspection of raw materials	6	3	3	54
	Raw materials already contaminated	8	4	4	128
	Poor packaging from supplier	7	3	3	63
Bent Needle Tip	Imprecise jig	7	4	4	112
	Improperly calibrated machine	6	3	4	72
	Operator error in cannula handling	8	5	3	120
	Suboptimal machine maintenance	6	3	4	72
	Raw needle material stored improperly	7	4	5	140
	Incorrect material placement into machine	6	4	3	72

FMEA analysis shows that primary risk priorities in A.V. Fistula production are Cannula Loose and Bent Needle Tip defects, with RPN ≥ 100 due to factors including dimensional non-conformance, weak joints, and operator errors. Scratch defects also show high RPN values related to sharp materials and insufficient operator awareness. Medium-risk causes (RPN 70–99) stem from irregular calibration and tool maintenance. These findings confirm the importance of focusing improvements on storage, calibration, operator training, and equipment cleanliness.

4. Improve

The Improve stage involved planning corrections for identified problems and proposing improvement actions using the 5W+1H method.

Table 6. 5W + 1H Method Improvement Plan

No	5W + 1H Aspect	Explanation
1	What (What will be improved?)	Improve high-RPN defect causes: sharp materials stored carelessly (RPN=160); tube dimensions occasionally non-conforming (RPN=180); contaminated materials (RPN=128); operator handling errors (RPN=140).
2	Why (Why is improvement necessary?)	RPN values indicate high failure risk, which may cause significant losses and reduce A.V. Fistula product quality. To reduce defects from 148,682 pcs (0.31% of 49,813,422 pcs) towards the zero-defect target.
3	Where (Where will improvements be made?)	Material storage & handling; cannula assembly; visual check & packaging process; automated/manual machines.
4	When (When will improvements be made?)	Carried out in stages, starting from the first week of the following month after FMEA analysis. Improvement priorities determined by highest RPN value first.
5	Who (Who is responsible?)	Production Team: implement updated SOPs and initial inspections. QA Team: verify improvement results. Engineering/Maintenance:

		recalibrate machines and repair tools. PPIC and Warehouse: ensure materials received and stored to quality and cleanliness standards.
6	How (How will improvements be made?)	Scratch: redesign box/tray with separating slots; replace worn machine parts; implement daily inspection checklists. Cannula Loose: use automated pull test with alarm; stricter tube dimension checks; low-adhesive alarm system. Foreign Particle: UV/oblique light for visual check; stricter incoming material inspection including particle contamination testing. Bent Needle Tip: store raw materials in safe, clean racks with foam protection; AOI visual camera warning system.

The 5W+1H approach is applied systematically to formulate RPN-priority-based improvement plans. Focus is directed at primary defect sources, with practical steps such as tray redesign, enhanced automated testing tools, and visual inspection. Cross-functional collaboration (production, QA, engineering, warehouse) and phased implementation make the improvement plan realistic and measurable. Overall, this strategy confirms the commitment to reducing defects toward zero-defect through prevention, procedure strengthening, and technological support.

5. Control

The Control stage ensures all improvement proposals from the Improve stage are implemented consistently through structured monitoring aligned with defect characteristics. Tray redesign for Scratch is controlled through monitoring of assistive tools, while Cannula Loose is supervised with automated pull tests, alarms, and periodic calibration. Foreign Particle and Bent Needle Tip defects are controlled through cleanliness maintenance, proper storage, and visual inspection. This stage validates improvement implementation while strengthening quality continuity toward zero-defect.

Comparison of Results Before and After Improvement

Table 7. Before Improvement: Production Output and Defect Category (Apr 2023–Mar 2024)

Month	Production	Scratch	Cannula Loose	Foreign Particle	Bent Needle Tip	Total Defect
Apr-23	4,872,134	5,660	2,105	7,200	1,200	16,165
May-23	5,563,545	9,250	1,142	2,800	3,440	16,632
Jun-23	5,657,746	7,110	1,130	5,640	2,300	16,180
Jul-23	5,504,910	7,368	2,111	1,200	4,405	15,084
Aug-23	5,438,991	6,460	1,364	1,040	4,240	13,104
Sep-23	4,222,953	4,200	997	1,220	3,105	9,522
Oct-23	4,168,785	5,426	1,445	1,020	4,600	12,491
Nov-23	3,410,163	3,300	1,210	1,100	1,430	7,040
Dec-23	2,911,810	2,535	1,163	1,350	4,462	9,510
Jan-24	2,862,757	7,450	1,214	2,200	1,722	12,586

Feb-24	2,571,910	3,221	2,116	1,440	4,600	11,377
Mar-24	2,627,718	1,600	1,108	1,620	4,663	8,991
Total	**49,813,422**	**63,580**	**17,105**	**27,830**	**40,167**	**148,682**

Note: the overall defect rate before improvement was 0.31% (148,682 defects out of 49,813,422 units produced).

Table 8. Before Improvement: DPMO and Sigma Values

Month	Production	Defects	DPU	DPMO	Sigma Level
Apr-23	4,872,134	16,165	0.0008	829.46	4.65
May-23	5,563,545	16,632	0.0007	747.36	4.68
Jun-23	5,657,746	16,180	0.0007	714.94	4.69
Jul-23	5,504,910	15,084	0.0007	685.02	4.70
Aug-23	5,438,991	13,104	0.0006	602.31	4.74
Sep-23	4,222,953	9,522	0.0006	563.70	4.76
Oct-23	4,168,785	12,491	0.0007	749.07	4.68
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Dec-23	2,911,810	9,510	0.0008	816.50	4.65
Jan-24	2,862,757	12,586	0.0011	1,099.11	4.56
Feb-24	2,571,910	11,377	0.0011	1,105.89	4.56
Mar-24	2,627,718	8,991	0.0009	855.40	4.64

Table 9. After Improvement: Production Output and Defect Category (Jan–Mar 2025)

Month	Production	Scratch	Cannula Loose	Foreign Particle	Bent Needle Tip	Defect Rate
Jan-25	3,820,900	2,373	873	2,485	972	0.18%
Feb-25	3,750,600	1,131	747	4,122	1,564	0.20%
Mar-25	3,973,200	3,620	986	2,600	1,384	0.22%
Total	**11,544,700**	**7,124**	**2,606**	**9,207**	**3,920**	**0.20%**

Table 10. After Improvement: DPMO and Sigma Values

Month	Production	Total Defects	DPU	DPMO	Sigma Level
Jan-25	3,820,900	6,703	0.0004	438.57	4.82
Feb-25	3,750,600	7,564	0.0005	504.18	4.78
Mar-25	3,973,200	8,590	0.0005	540.49	4.76
Average				**471.38**	**4.80**

Based on Tables 7–8, the average defect rate before improvement was 0.31% with an average sigma value of 4.67. Tables 9–10 show that after implementing improvement proposals from January to March 2025, the defect rate decreased significantly to an average of 0.20% a reduction of 0.11% while the sigma value increased to an average of 4.80. This reduction reflects genuine improvement in production process effectiveness and quality control, and indicates that the implemented corrective actions are achieving the planned quality improvement targets.

DISCUSSION

The implementation of the Six Sigma DMAIC methodology at PT. XYZ has demonstrated a measurable and statistically significant improvement in the quality control of A.V. Fistula products. The reduction in the average defect rate from 0.31% to 0.20%—a relative decrease of approximately 35.5% and the corresponding increase in the sigma level from 4.67 to 4.80 confirm that the structured, data-driven approach of DMAIC is highly effective in identifying and mitigating the root causes of defects in medical device manufacturing. This finding is consistent with previous research conducted by Hairiyah & Amalia (2020) and Ridho et al. (2022), who reported similar improvements in product quality across different industrial sectors using the same methodology. However, what distinguishes this study is its application within the highly regulated medical device industry, where ISO 13485 compliance and patient safety impose stricter quality requirements than general manufacturing contexts. This contextual factor amplifies the significance of the results, as even minor defect rate reductions can have substantial implications for patient outcomes and regulatory standing.

A deeper examination of the Pareto analysis reveals that Scratch defects accounted for 42.8% of total non-conformities, making it the most critical quality issue. This dominance can be attributed to the nature of the production process, which involves multiple manual handling stages, exposure to sharp tools, and the use of packaging materials with rough surfaces. The fishbone diagram analysis further corroborated this by identifying human factors such as insufficient operator training and lack of awareness as primary contributors. This finding aligns with the work of Ansori & Gusniar (2023), who emphasized that human error remains the most pervasive source of variability in labor-intensive manufacturing processes. The practical implication is that investments in operator training, standardized handling procedures, and ergonomic tool design may yield higher returns than technological interventions alone, particularly in the short term.

The FMEA analysis provided a critical risk-prioritization framework that guided the allocation of improvement resources. Failure modes with RPN values exceeding 100 specifically Cannula Loose (RPN = 180), Bent Needle Tip (RPN = 160), and Scratch related to sharp material storage (RPN = 160)—were rightfully prioritized. The high RPN for Cannula Loose was driven by both severity (potential device failure during medical use) and occurrence (frequent assembly inconsistencies), making it a high-impact target for improvement. This risk-based approach is particularly valuable in the medical device sector, where the cost of failure extends beyond financial losses to include patient morbidity and legal liability. The subsequent implementation of automated

pull-test systems and precision measurement tools directly addressed these high-risk failure modes, which is reflected in the post-improvement data showing a substantial decline in Cannula Loose and Bent Needle Tip defects. This observation supports the findings of Anggita et al. (2021), who demonstrated that integrating FMEA with Six Sigma enhances the effectiveness of corrective actions by ensuring that efforts are concentrated on the most consequential quality issues.

Another noteworthy aspect of this study is the apparent contradiction observed in the P-control chart during the Measure phase. Although all data points remained within the UCL and LCL boundaries indicating statistical control the presence of outlier values in January and February 2024 suggested underlying process instability. This discrepancy highlights a critical limitation of relying solely on statistical control charts without complementary diagnostic tools. The subsequent fishbone and FMEA analyses were instrumental in uncovering the latent root causes that statistical process control alone could not detect. This finding reinforces the argument made by Suseno & Ashari (2022) that Six Sigma's strength lies not in any single analytical tool but in the synergistic integration of multiple tools across the DMAIC phases. It also underscores the importance of managerial judgment and domain expertise in interpreting statistical outputs, particularly in complex manufacturing environments where multiple interacting factors contribute to quality deviations.

The improvement actions implemented during the Improve stage including jig redesign, daily machine checklists, material inspection using microscopy and UV light, and cross-departmental supervision represent a balanced approach combining engineering controls, procedural standardization, and human factor interventions. The 5W+1H framework ensured that each corrective action was specific, measurable, and accountable, which increased the likelihood of successful implementation. Notably, the adoption of automated visual inspection systems addressed the limitation of human inspection, which is prone to fatigue and inconsistency, particularly in high-volume production settings. This technological upgrade is consistent with the broader industry trend toward Industry 4.0 and smart manufacturing, where real-time quality monitoring and data analytics enable proactive rather than reactive quality management (Budiarto, 2021). However, it is important to acknowledge that technological solutions are not a panacea; their effectiveness depends on proper calibration, maintenance, and operator competency factors that were incorporated into the Control stage through structured monitoring protocols.

The Control stage, which involved ongoing monitoring of assistive tools, automated pull tests, cleanliness maintenance, and visual inspection, serves as the linchpin for sustaining the achieved improvements. The post-improvement data from January to March 2025 indicate that the gains were not merely transient but have been maintained over a three-month period, suggesting that the implemented controls are robust and well-integrated into routine operations. Nevertheless, the sigma level of 4.80, while an improvement, still falls short of the six-sigma benchmark (3.4 DPMO). This gap implies that further opportunities for optimization exist, particularly in addressing the remaining defect categories and reducing process variation at the micro-level. Continuous improvement efforts should therefore focus on refining existing controls, exploring

advanced statistical techniques such as Design of Experiments (DOE), and fostering a quality-centric organizational culture through leadership commitment and employee engagement (Gaspersz, 2007). From a practical perspective, this study offers a replicable framework for other medical device manufacturers facing similar quality challenges. The integration of Pareto analysis, fishbone diagrams, FMEA, and statistical process control within the DMAIC structure provides a comprehensive toolkit that can be adapted to different product types and production scales. Moreover, the emphasis on cross-functional collaboration involving production, quality assurance, engineering, and warehouse departments underscores the importance of breaking down silos and promoting shared accountability for quality outcomes. This collaborative approach is particularly relevant in the medical device industry, where product quality is a shared responsibility across the entire value chain, from raw material procurement to final product distribution (Rini, 2022).

Despite the positive results, this study has several limitations that should be acknowledged. First, the post-improvement monitoring period was relatively short (three months), which may not fully capture long-term sustainability or seasonal variations in production conditions. Second, the research was confined to a single product line (A.V. Fistula) at a single manufacturing site, which limits the generalizability of the findings to other products or facilities. Third, while the study identified and addressed several root causes, the potential for interaction effects among different defect types was not systematically explored. Future research should extend the monitoring period to at least one full production cycle, apply the Six Sigma methodology to multiple product lines to assess its scalability, and investigate the synergistic effects of multiple defect causes using advanced multivariate analysis techniques. Additionally, incorporating cost-benefit analysis of the improvement initiatives would provide valuable insights into the economic viability and return on investment of Six Sigma implementation, which is a critical consideration for management decision-making.

In conclusion, the discussion confirms that the Six Sigma DMAIC methodology is not only effective in reducing defect rates and improving process capability in A.V. Fistula production but also provides a robust framework for fostering a culture of continuous quality improvement. The success of this implementation at PT. XYZ serves as a compelling case for broader adoption across the organization and offers practical lessons for the medical device manufacturing industry at large. However, sustained excellence requires unwavering commitment, systematic monitoring, and a willingness to adapt to emerging challenges principles that are fundamental to the philosophy of Six Sigma and total quality management

CONCLUSIONS

Quality control research on A.V. Fistula products at PT. XYZ Batam using the Six Sigma (DMAIC) method demonstrated that product quality is influenced by four main factors: machine, human, method, and material. Analysis identified dominant defect causes including uncalibrated machines, insufficient operator skill, inconsistent work methods, and substandard materials.

Through the Improve and Control stages, the company implemented solutions including jig redesign, daily machine checklists, material inspection using microscopy/UV light, and cross-departmental supervision. Implementation results show a reduction in average defect rate from 0.31% (σ = 4.67) to 0.20% (σ = 4.80), confirming that Six Sigma is effective in reducing process variation, improving quality, and supporting the continuous achievement of zero defect.

For ongoing quality improvement of A.V. Fistula products at PT. XYZ Batam, the following recommendations are proposed: (1) enhance preventive maintenance, routine calibration, and machine cleanliness; (2) provide regular training to improve operator skills and quality awareness; (3) standardize operational procedures through clear SOPs and compliance audits; (4) tighten incoming material inspections, storage management, and supplier cooperation; (5) conduct continuous monitoring and evaluation of improvement effectiveness; and (6) expand Six Sigma implementation to all production lines to strengthen the culture of continuous improvement and maintain long-term quality.

This study is subject to certain limitations that should be considered when interpreting the results. The post-improvement monitoring period was limited to three months (January–March 2025), which may not fully capture the long-term sustainability of the improvements achieved; future studies are therefore recommended to extend the monitoring period across at least one full production cycle. In addition, this study did not include a cost-benefit or return-on-investment analysis of the corrective actions implemented. Incorporating such an economic analysis in future research would provide valuable insight into the financial viability of Six Sigma implementation and would strengthen the basis for management decision-making regarding continued investment in quality improvement initiatives.

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