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Risk-Based Quality Improvement Using FMEA and Six Sigma DMAIC to Enhance Manufacturing Process Reliability

Miko Mei Irwanto[1*], Atiek Ike Wijayanti[2], Ahmad Fauzi Pane.[3], Doni Suseno[4]
[1,2,3,4] Sekolah Tinggi Teknologi (STT) Bina Tunggal, Bekasi, Indonesia

miko.irwanto@gmail.com*

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Abstract

Manufacturing firms that work under tight tolerances and delivery schedules still suffer from recurrent defects that erode process reliability, yet many improvement projects either quantify variation without prioritizing risk or rank risk without verifying statistical performance. This study develops and tests a risk-based quality improvement framework that embeds Failure Mode and Effects Analysis (FMEA) into every phase of the Six Sigma Define–Measure–Analyze–Improve–Control (DMAIC) cycle. A single-case explanatory design was applied in an automotive stamping and spot-welding component plant in Bekasi, Indonesia, using twelve months of production records, measurement system analysis, process capability studies, and a cross-functional FMEA panel that compared the Risk Priority Number (RPN) with AIAG–VDA Action Priority. In the baseline period, 5,236 defects were recorded in 184,500 units, equivalent to 7,095 defects per million opportunities (DPMO) and a sigma level of 3.95. Eight failure modes were prioritized, led by edge burr, insufficient weld nuggets, and flange-height deviation. After preventive tooling maintenance, electrode tip-dressing, optimized weld parameters, poka-yoke, and statistical process control were implemented, DPMO fell to 2,677 (sigma 4.28), total RPN declined by 76.7%, and the Cpk of critical characteristics exceeded 1.33. The framework offers a replicable route for converting risk knowledge into sustained reliability gains.

INTRODUCTION

Manufacturing competitiveness is increasingly determined not only by cost and speed but by the reliability of the processes that convert materials into conforming products. In automotive supply chains, where component makers deliver in small lots under just-in-time schedules and zero-defect expectations, a single unstable operation can trigger line stoppages at the customer, costly containment, and loss of supplier rating. Process reliability, understood here as the ability of a process to produce conforming output consistently over time with a low probability of failure, has therefore become a strategic capability rather than a purely technical concern. Systematic reviews of the manufacturing literature show that structured improvement methods remain the main vehicle through which firms pursue this capability, with Lean Six Sigma reported to raise sigma levels, reduce non-value-added activities, and improve productivity across a wide range of

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industrial settings (Kumar et al., 2024). Case evidence from car-parts suppliers likewise confirms that the DMAIC roadmap can substantially reduce defects when it is applied with discipline and supported by data (Condé et al., 2023).

Six Sigma approaches quality as a problem of variation. Its DMAIC cycle (Define, Measure, Analyze, Improve, Control) provides a sequenced, evidence-based logic in which a problem is scoped, current performance is quantified in terms of defects per million opportunities (DPMO), sigma level, and process capability, root causes are identified statistically, solutions are tested, and gains are locked in through control mechanisms. Recent applications in Indonesian and international manufacturing illustrate the breadth of this logic, from injection moulding of medical equipment (Larisang et al., 2025) and plastic injection yield improvement (Hsiao et al., 2023) to new product launches in the white-goods industry, where DMAIC was combined with FMEA and design of experiments (Aktar Demirtaş et al., 2024). The strength of DMAIC lies in its measurement discipline: improvement claims are anchored in baseline and post-improvement data rather than in managerial impression.

Failure Mode and Effects Analysis (FMEA) addresses a different but complementary question: not how much a process varies, but where and how it can fail, how serious the consequences would be, and how likely the failure is to escape detection. In its classical form, each failure mode is rated for severity (S), occurrence (O), and detection (D), and the product of the three ratings yields the Risk Priority Number (RPN), which is used to rank improvement priorities. FMEA is therefore inherently preventive and forward-looking. Its weakness, widely discussed in the recent literature, is the subjectivity and mathematical crudeness of the RPN. Expert ratings depend on intuition and judgment (Cardiel-Ortega & Baeza-Serrato, 2023), and different combinations of S, O, and D can produce identical RPN values despite very different risk implications (Cebeci et al., 2025). Researchers have responded with fuzzy and entropy-weighted variants of the RPN for manufacturing settings (Krisnaningsih et al., 2022; Özden Gürcan, 2026; Shakibaei et al., 2025), while industry has moved toward the harmonized AIAG–VDA approach, in which the RPN is replaced by an Action Priority (AP) logic that gives severity the greatest weight (Barsalou, 2022; Jeluš et al., 2026).

Because Six Sigma is strong in measurement but comparatively weak in anticipating failures, and FMEA is strong in anticipation but weak in statistical verification, integrating the two has become a popular strategy. Godina et al. (2021) showed in the automotive sector that a fuzzy FMEA embedded in DMAIC produced a more discriminating risk ranking than the classical RPN. Indonesian studies report similar benefits: Six Sigma–FMEA projects have lowered DPMO and raised sigma levels in the production of putty (Soejanto & Ekawati, 2024), cosmetic tube packaging (Oxamudra et al., 2025), water-inlet pipes (Fadhlullah et al., 2024), orthopaedic bone plates using a fuzzy FMEA (Rizkyllah & Aryanny, 2025), and flange management in the oil and gas industry, where rework fell from 18.6% to 3.9% (Situmorang & Irwan, 2026). These studies collectively demonstrate that combining variation reduction with risk prioritization yields measurable quality gains.

At the same time, the broader operational excellence literature is reframing continuous improvement around digitalization and data. Reviews of Lean Six Sigma and Industry 4.0 identify strong synergies between the two (Antony et al., 2023; Skalli et al., 2023), map specific contact points between improvement practices and digital technologies (Sordan et al., 2022), and explain how quality-related methodologies can be integrated with Industry 4.0 at the operational level (Komkowski et al., 2023). Empirical work from Italian manufacturers shows that firms with a mature Lean Six Sigma culture find it easier to absorb digital technologies (Chiarini & Kumar, 2021), although integration barriers such as high implementation cost, a long learning curve, and technological incompatibility remain significant (Macias-Aguayo et al., 2022). Newer frameworks also link these programs to circularity and sustainability goals (Skalli et al., 2024). For small and medium-sized component makers in emerging economies, however, the immediate challenge is usually more basic: building a reliable, data-driven risk discipline on the shop floor that can later be

digitalized.

A close reading of the integration literature reveals three gaps. First, most Six Sigma–FMEA studies use FMEA as a single tool inside the Analyze phase, typically to rank causes after a Pareto and fishbone analysis. FMEA is rarely treated as a living risk layer that runs through all five phases, from scoping in Define to the control plan in Control, so the logic that connects measured variation to risk and back to control is left implicit. Second, the large majority of applied studies still rely exclusively on the classical RPN, even though the AIAG–VDA handbook has shifted practice toward Action Priority, and empirical comparisons of the two prioritization logics within a complete DMAIC project remain scarce. Third, many studies report improvement in DPMO or sigma level alone, without simultaneously verifying the measurement system, the change in process capability (Cpk) of critical characteristics, the statistical significance of the defect reduction, and the reduction in residual risk. Without these elements, claims about enhanced "process reliability" rest on incomplete evidence, and practitioners have little guidance on whether the gains will persist once the project team disbands.

The novelty of this study lies in addressing these gaps together. It proposes and tests a phase-embedded FMEA–DMAIC framework in which each DMAIC phase has a defined FMEA counterpart, so that risk information is generated, calibrated, acted upon, re-rated, and institutionalized in a continuous chain. The study applies both RPN and AIAG–VDA Action Priority to the same set of failure modes and examines where the two logics agree and diverge, providing practical evidence for manufacturers transitioning between FMEA standards. Finally, it evaluates reliability through a multi-indicator lens that combines DPMO, sigma level, Cpk, a two-proportion significance test, and total residual RPN, and it does so in a stamping and spot-welding environment of an Indonesian automotive supplier, a context that remains underrepresented in the integration literature compared with packaging, food, and assembly processes.

In terms of stance, this study supports the general conclusion of earlier research that Six Sigma and FMEA are complementary, but it argues against treating FMEA as an auxiliary ranking tool confined to one phase. It also partly corrects the reliance on the classical RPN by showing that severity-weighted Action Priority can change which failure modes are treated as urgent. Accordingly, the objectives of this study are (1) to measure the baseline reliability of a stamping and welding process in terms of DPMO, sigma level, and process capability; (2) to identify and prioritize its failure modes using RPN and Action Priority; (3) to design and implement risk-based improvement actions through the DMAIC cycle; and (4) to evaluate the effect of these actions on defect performance, capability, and residual risk. The findings are expected to contribute a replicable framework for academics and a practical roadmap for quality engineers seeking to make process reliability measurable and sustainable.

METHODS

Research design and setting

This study used a single-case explanatory design with a quantitative pre–post comparison, a design commonly employed in DMAIC research because it allows the full improvement cycle to be observed within its real operating context (Condé et al., 2023; Larisang et al., 2025). The case was the bracket production line of an automotive component manufacturer in Bekasi, West Java, which produces rear-seat bracket assemblies through progressive-die stamping followed by resistance spot welding. The line was selected because its internal defect rate (2.84%) exceeded the customer target of 1.0% and because two customer complaints concerning weld strength had been received in the previous year. The study period covered January to December 2025, divided into a baseline period (January–June), an improvement period (July–September), and a control period (October–December).

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Data sources and measurement

Data were obtained from daily production and inspection reports, rework and scrap logs, customer complaint records, and dimensional measurements of critical-to-quality (CTQ) characteristics. Four CTQs were defined as defect opportunities per unit: edge quality (burr height ≤ 0.10 mm), flange height (25.0 ± 0.3 mm), weld nugget diameter (≥ 5.0 mm), and hole position (± 0.2 mm). Before the baseline was analyzed, the measurement system was verified through a crossed Gauge R&R study on flange height (three appraisers, ten parts, three trials) and an attribute agreement analysis for visual defects. Performance was expressed using defects per unit (DPU), DPMO, sigma level with the conventional 1.5σ shift, and the process capability index Cpk, consistent with prior Six Sigma–FMEA studies (Soejanto & Ekawati, 2024; Situmorang & Irwan, 2026).

FMEA procedure

A cross-functional team of seven members (production, quality, maintenance, process engineering, and tooling) developed a process FMEA following the seven-step logic of the AIAG–VDA handbook: planning, structure analysis, function analysis, failure analysis, risk analysis, optimization, and documentation (Jeluš et al., 2026). Severity, occurrence, and detection were rated on 1–10 scales; ratings were assigned by consensus after a calibration session, and occurrence ratings were anchored to observed baseline defect frequencies to reduce subjectivity (Cardiel-Ortega & Baeza-Serrato, 2023). For every failure mode, both the RPN (S × O × D) and the Action Priority category (High, Medium, Low) were determined, so that the two prioritization logics could be compared (Barsalou, 2022). Failure modes with AP = High or RPN ≥ 150 were assigned mandatory actions.

DMAIC–FMEA framework and analysis

The research followed the phase-embedded framework shown in Image 1. In each DMAIC phase, the Six Sigma activities and the corresponding FMEA activities were conducted in parallel and exchanged information: Define set the FMEA scope; Measure calibrated rating scales against measured data; Analyze generated failure mode–cause chains and risk rankings; Improve implemented risk-ranked countermeasures, including a design of experiments on weld parameters, and re-rated the FMEA; and Control converted the updated FMEA into a control plan with statistical process control (SPC). The effect of the intervention was tested with a two-proportion z-test comparing baseline and control-period defect rates at $\alpha = 0.05$, and capability was recalculated for the critical characteristics. Data were processed using Minitab 21 and Microsoft Excel.

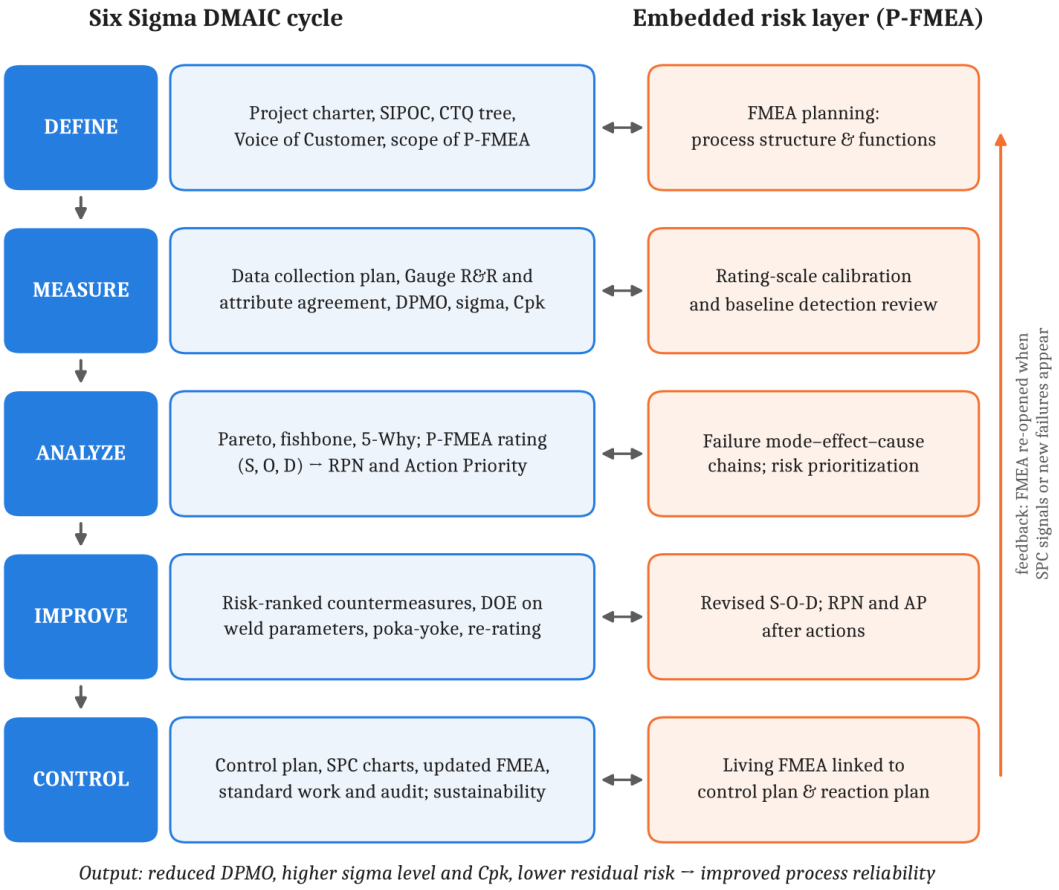


Image 1. Phase-embedded FMEA–Six Sigma DMAIC research framework
Source: Developed by the authors (2026)

RESULTS AND DISCUSSION

Define and measure: baseline reliability

The Define phase produced a project charter targeting a 50% reduction in DPMO within six months, together with a SIPOC map that located the main risks in the trimming, flanging, piercing, and spot-welding operations. The voice of the customer was translated into the four CTQ characteristics described above. In the Measure phase, the Gauge R&R study on flange height yielded a total measurement variation of 8.6% of the study variation with ten distinct categories, and the attribute agreement analysis yielded a Fleiss' kappa of 0.87. Both results fall within commonly accepted limits, indicating that subsequent variation could be attributed to the process rather than to measurement error.

Table 1 summarizes the baseline defect structure. During the six-month baseline period, the line produced 184,500 units and recorded 5,236 defects. Three defect types, namely burr on the trimmed edge, flange-height deviation, and insufficient weld nugget, accounted for 81.3% of all defects, confirming a strong Pareto pattern that justified focusing the project on the stamping die and the welding station.

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Table 1. Baseline defect distribution, January–June 2025

Defect type	CTQ affected	Frequency	Percentage (%)	Cumulative (%)
Burr on trimmed edge	Edge quality	1,812	34.6	34.6
Flange-height deviation	Flange height	1,440	27.5	62.1
Insufficient weld nugget	Weld nugget diameter	1,005	19.2	81.3
Surface scratch / dent	Edge quality (visual)	612	11.7	93.0
Hole position out of tolerance	Hole position	367	7.0	100.0
Total		**5,236**	**100.0**	

Source: Production and inspection records, processed by the authors (2026)

Baseline performance indicators are presented in Table 2. With four opportunities per unit, the process operated at 7,095 DPMO, corresponding to a sigma level of 3.95. Capability studies showed that the two continuous CTQs were not capable: the Cpk of flange height was 0.82 and that of weld nugget diameter was 0.94, both well below the automotive benchmark of 1.33. The flange-height data also showed a mean shift toward the upper specification limit, which suggested a systematic die-setting problem rather than purely random variation. These figures are in the same range as the baseline values reported in comparable Indonesian manufacturing cases, where sigma levels between 3.3 and 3.9 were common before improvement (Rizkyllah & Aryanny, 2025; Situmorang & Irwan, 2026), indicating that the case was representative of the reliability problems faced by local suppliers.

Table 2. Baseline process performance indicators

Indicator	Value	Benchmark / target	Interpretation
Units produced	184,500	–	Six-month baseline
Opportunities per unit	4	–	Four CTQ characteristics
Total defects	5,236	–	From inspection records
Defects per unit (DPU)	0.0284	≤ 0.010	Above customer target
DPMO	7,095	≤ 3,500 (project target)	Moderate performance
Sigma level	3.95	≥ 4.20	Below target
Cpk flange height	0.82	≥ 1.33	Not capable
Cpk weld nugget diameter	0.94	≥ 1.33	Not capable
Gauge R&R (% study variation)	8.6	< 10	Acceptable
Attribute agreement (Fleiss' kappa)	0.87	≥ 0.75	Acceptable

Source: Production records and capability studies, processed by the authors (2026)

Analyze: failure modes and risk prioritization

Root cause analysis using fishbone diagrams and 5-Why sessions produced 23 potential causes, which the FMEA team consolidated into eight failure mode–cause chains. Table 3 presents the resulting process FMEA. Excessive burr ranked first by RPN (288), driven by high occurrence related to punch–die clearance wear and the absence of a regrinding interval. Insufficient weld nugget ranked second (RPN 270) and carried the highest severity rating (S = 9) because a weak weld can compromise seat-anchorage strength and thus vehicle safety. Flange-height deviation ranked third (RPN 245), caused by coil thickness variation and die setting based on operator experience.

The distribution of causes across the fishbone categories was also informative. Of the

23 potential causes, nine were related to machines and tooling, six to methods, four to materials, three to people, and one to the measurement environment. The dominance of machine and method causes indicated that the defects were largely systemic, arising from the absence of preventive maintenance intervals and standardized settings, rather than from individual operator carelessness. This finding shaped the improvement strategy: instead of relying on additional inspection or operator retraining alone, the team concentrated on preventive controls that would reduce occurrence at the source and on detection controls that would make residual failures visible before parts left the station.

Table 3. Process FMEA before improvement

No.	Failure mode	Main cause	S	O	D	RPN	AP
FM1	Excessive burr on trimmed edge	Punch–die clearance wear; no regrind interval	6	8	6	288	H
FM2	Flange-height deviation	Coil thickness variation; experience-based die setting	7	7	5	245	H
FM3	Insufficient weld nugget	Electrode tip mushrooming; no tip-dressing schedule	9	5	6	270	H
FM4	Hole position out of tolerance	Pilot pin wear; strip misfeed	8	4	5	160	H
FM5	Surface scratch / dent	Slug and debris on die surface; bulk bin handling	4	6	4	96	M
FM6	Weld spatter / expulsion	Excessive current; poor part fit-up	5	5	4	100	M
FM7	Wrong part orientation in welding jig	No error-proofing on jig	8	3	7	168	H
FM8	Missing pierced hole	Broken punch not detected	8	2	6	96	M
	Total RPN					**1,423**	

Source: FMEA team assessment, processed by the authors (2026)

The comparison of RPN and Action Priority produced an important insight. Both logics placed FM1, FM2, and FM3 in the highest priority group, but they diverged for FM7 and FM8. Wrong part orientation in the welding jig (FM7) had a moderate RPN of 168 yet received AP = High because of its severity (S = 8) combined with weak detection (D = 7); under a conventional RPN threshold of 200, which many plants still use, this failure mode would not have received mandatory action. Conversely, FM5 and FM6 had RPN values close to that of FM8, yet all three were classified as Medium. This pattern supports the argument that identical or similar RPN values can hide qualitatively different risks (Cebeci et al., 2025) and is consistent with the observation that severity-weighted prioritization changes the composition, not merely the number, of required actions (Barsalou, 2022). In practical terms, the AP logic redirected the team's attention toward a low-frequency but safety-relevant failure that the RPN alone would have deprioritized.

Improve: risk-based countermeasures

Countermeasures were designed for every High-priority failure mode and for the Medium items where low-cost actions were available. Table 4 lists the actions and the revised ratings. For FM1, a preventive regrinding interval of 25,000 strokes and a clearance check at each die change were introduced. For FM2, an incoming coil-thickness check and a standardized die-setting procedure using shim blocks replaced experience-based adjustment. For FM3, a tip-dressing schedule every 250 welds, a current-stepper function, and a destructive chisel test at the start of each shift were implemented. A two-level full factorial experiment on weld current, weld time, and electrode force identified 9.5 kA, 12 cycles, and 2.8 kN as the setting that maximized nugget diameter without expulsion, which

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also addressed FM6. Error-proofing pins on the welding jig (FM7) and a punch-break sensor in the die (FM8) eliminated the possibility of the two failures reaching the customer.

Table 4. Improvement actions and revised FMEA ratings

No.	Main improvement action	S	O	D	RPN after	AP after	RPN change (%)
FM1	Regrind every 25,000 strokes; clearance check at die change	6	3	3	54	L	-81.3
FM2	Coil thickness check; shim-block die-setting SOP; X̄–R chart	7	3	3	63	L	-74.3
FM3	Tip dressing every 250 welds; current stepper; chisel test per shift	9	2	3	54	M	-80.0
FM4	Pilot pin replacement schedule; misfeed sensor	8	2	3	48	M	-70.0
FM5	Air-blow die cleaning; separator trays	4	3	3	36	L	-62.5
FM6	DOE-optimized weld schedule (9.5 kA, 12 cycles, 2.8 kN)	5	3	3	45	L	-55.0
FM7	Poka-yoke locating pins on welding jig	8	1	2	16	L	-90.5
FM8	Punch-break sensor interlocked with press	8	1	2	16	L	-83.3
	Total RPN				**332**		**-76.7**

Source: FMEA team re-assessment, processed by the authors (2026)

Severity ratings did not change because the actions targeted the causes and controls rather than the design of the part, which is consistent with FMEA convention. The reductions were achieved through lower occurrence (prevention) and better detection (control), and total RPN fell from 1,423 to 332, a reduction of 76.7%. FM3 and FM4 remained at AP = Medium because their severity stayed high, which signalled to the team that these two failure modes should remain under heightened monitoring in the control plan rather than being regarded as closed.

Control: sustained performance and reliability

In the Control phase, the updated FMEA was translated into a control plan that specified the characteristic, method, sample size, frequency, and reaction plan for each CTQ. X̄–R charts were introduced for flange height and nugget diameter, and a p-chart was used for the overall defect proportion. Layered process audits were scheduled weekly, and the FMEA was designated a living document to be reopened whenever an SPC signal, a customer complaint, or a process change occurred. Image 2 compares the defect rates by type in the baseline and control periods, normalized per 10,000 units because the periods differed in length.

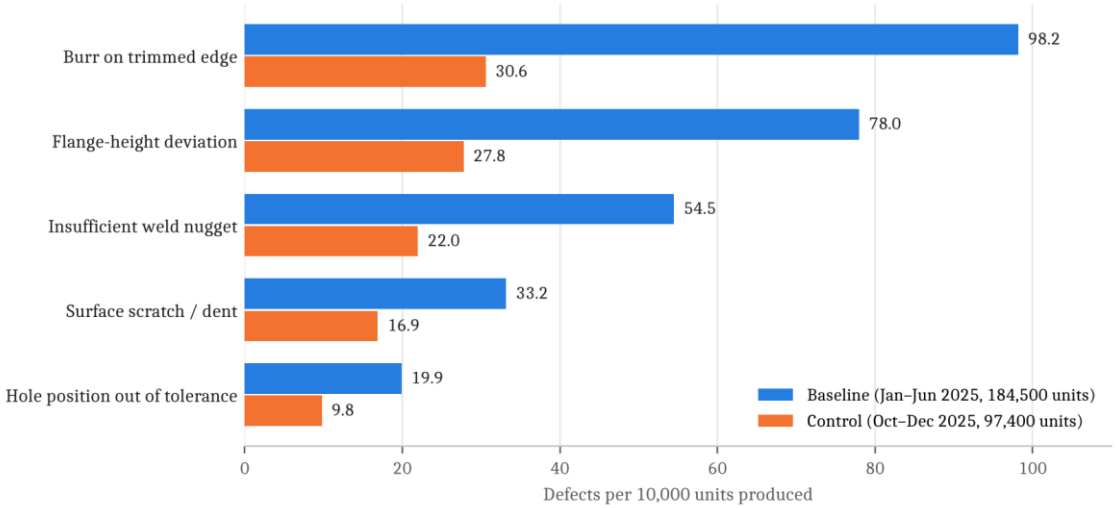


Image 2. Defects per 10,000 units by defect type, baseline versus control period

Source: Production and inspection records, processed by the authors (2026)

Every defect category declined, and the largest reductions occurred in the three categories targeted by the highest-priority actions: burr fell from 98.2 to 30.6 defects per 10,000 units, flange-height deviation from 78.0 to 27.8, and insufficient weld nugget from 54.5 to 22.0. Table 5 summarizes the overall change in reliability indicators.

Table 5. Process performance before and after implementation

Indicator	Baseline (Jan–Jun)	Improve (Jul–Sep)	Control (Oct–Dec)	Change (baseline–control)
Units produced	184,500	96,800	97,400	–
Total defects	5,236	1,162	1,043	–
Defect rate (%)	2.84	1.20	1.07	-62.3%
DPMO	7,095	3,001	2,677	-62.3%
Sigma level	3.95	4.25	4.28	+0.33
Cpk flange height	0.82	1.29	1.38	+0.56
Cpk weld nugget diameter	0.94	1.36	1.45	+0.51
Total RPN	1,423	332	332	-76.7%
Customer complaints	1	0	0	–

Source: Production records and FMEA documents, processed by the authors (2026)

The defect proportion fell from 2.84% to 1.07%, and the two-proportion z-test confirmed that this reduction was statistically significant ($z = 30.23$, $p < 0.001$). DPMO decreased by 62.3%, exceeding the 50% target in the project charter, and the sigma level rose from 3.95 to 4.28. More importantly for reliability, both continuous CTQs became capable, with Cpk values above 1.33, meaning the process could now meet specifications consistently rather than relying on inspection to sort conforming parts. Performance in the control period was slightly better than in the improvement period, indicating that the gains were sustained rather than temporary, a result that many DMAIC projects fail to demonstrate because measurement stops at the Improve phase.

Discussion

The results support the central proposition that FMEA and Six Sigma are more powerful when FMEA functions as a continuous risk layer rather than a single analytical

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tool. In this case, the Measure phase improved the FMEA by anchoring occurrence ratings to measured frequencies and by verifying that detection controls were capable, while the FMEA improved the Six Sigma project by directing improvement effort toward failure modes whose consequences, not only frequencies, were serious. This mutual reinforcement explains why the reduction in residual risk (76.7%) was larger than the reduction in DPMO (62.3%): several actions, notably poka-yoke and the punch-break sensor, sharply reduced the probability of a defect reaching the customer even where they contributed relatively little to the in-process defect count.

The magnitude of improvement is comparable with earlier integration studies. Soejanto and Ekawati (2024) reported a rise in sigma level from 3.48 to 3.98, and Situmorang and Irwan (2026) reported a fall in rework from 18.6% to 3.9%; the present gain of 0.33 sigma from a higher starting point is consistent with the general observation that improvement becomes harder as processes approach four sigma. The findings also parallel automotive evidence that DMAIC delivers durable defect reduction when supported by statistical tools and standardized work (Condé et al., 2023). What distinguishes the present study is the explicit verification of measurement capability, process capability, statistical significance, and residual risk within one framework, which together provide a more defensible basis for claiming improved process reliability than DPMO alone.

The divergence between RPN and Action Priority has practical implications for manufacturers. The case shows that relying on an RPN threshold could have left a safety-relevant orientation error untreated, whereas the severity-weighted AP logic captured it. This supports the shift toward the AIAG–VDA approach (Jeluš et al., 2026) and complements fuzzy and entropy-based refinements, which pursue the same goal of more discriminating prioritization through different mathematical means (Godina et al., 2021; Shakibaei et al., 2025). For small and medium-sized suppliers, AP offers an advantage in being simpler to apply than fuzzy inference while still correcting the most serious weakness of the RPN. From a managerial perspective, the case also suggests that the main barrier to reliability was organizational rather than technical: most effective countermeasures were inexpensive, but they required clear ownership, defined maintenance intervals, and a review rhythm that kept the FMEA current. Embedding FMEA reviews in routine production meetings proved as important as the analytical tools themselves.

The framework also creates a foundation for digitalization. The control plan, SPC charts, and living FMEA generate structured data streams that can later be connected to sensors and dashboards, in line with the integration pathways described in the Lean Six Sigma 4.0 literature (Antony et al., 2023; Skalli et al., 2023). The study nevertheless has limitations. It examined a single production line over twelve months, so generalization to other processes should be made cautiously; FMEA ratings remain partly judgmental despite calibration; and the cost–benefit dimension was not analyzed in detail. Future research could replicate the framework across multiple plants, combine Action Priority with fuzzy or data-driven occurrence estimation, and evaluate the economic return and sustainability effects of risk-based improvement.

CONCLUSIONS

This study demonstrates that embedding FMEA in every phase of the Six Sigma DMAIC cycle is an effective route to enhancing manufacturing process reliability. In the case of an automotive stamping and spot-welding line, the integrated framework reduced DPMO from 7,095 to 2,677, raised the sigma level from 3.95 to 4.28, increased the Cpk of critical characteristics above 1.33, and lowered total residual risk by 76.7%, with the improvement proving statistically significant and stable during the control period. The comparison of prioritization logics showed that severity-weighted Action Priority can reveal safety-relevant failure modes that the classical RPN underestimates. Conceptually, the study contributes a phase-embedded FMEA–DMAIC model and a multi-indicator approach to assessing reliability; practically, it gives quality engineers a replicable roadmap that links

measured variation, prioritized risk, targeted countermeasures, and institutionalized control. Its impact extends beyond defect reduction to stronger supplier credibility and a data foundation for future digital quality management.

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