Improving Production Fixture Availability Using Lean and Six Sigma in a Medical Device Manufacturing Line

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Abstract *– This design project addressed the problem of production fixture unavailability in a medical device manufacturing line, where missing, misplaced, or delayed fixtures generated avoidable downtime and process interruptions. The main objective was to improve fixture availability and reduce fixture-related downtime through the application of Lean and Six Sigma principles. The methodology followed an applied, non-experimental, observational approach using historical downtime records, fixture usage logs, direct observations, process mapping, cause-and-effect analysis, and statistical evaluation of key performance indicators. The results showed that missing fixtures, misplaced fixtures, and waiting for fixture return were the most frequent baseline causes. Comparative analysis between baseline and post-improvement conditions showed a reduction in mean downtime from 37.53 to 13.53 minutes, a reduction in interruptions from 4.40 to 1.73, and an increase in fixture availability from 80.93% to 95.00%. These findings support the conclusion that a structured fixture management strategy can improve operational efficiency and process stability.*

Keywords *– Fixture Availability, Lean Six Sigma, Medical Device Manufacturing, Production Downtime.*

INTRODUCTION

In medical device manufacturing, even short production interruptions may generate significant losses in capacity, labor efficiency, and operational cost. One recurrent source of disruption is the unavailability of production fixtures when operators need them to complete setup, inspection, or process execution activities. In this type of environment, fixtures are critical support elements because they help ensure consistency, repeatability, and compliance throughout the production process. When fixtures are missing, misplaced, delayed, or unavailable at the point of use, the production flow is interrupted, and operational performance is affected.

The problem addressed in this design project was that the current process for managing production fixtures in a selected medical device manufacturing line did not guarantee fixture availability at the point of use. As a consequence, operators frequently had to wait for fixtures, search for them, borrow them from other stations, or adapt the workflow in ways that increased downtime and process variability. This condition reduced efficiency and made it more difficult to maintain stable production performance.

The objective of this work was to improve production fixture availability and reduce fixture-related downtime through the application of Lean and Six Sigma principles. More specifically, the project aimed to document the current fixture management process, quantify the impact of fixture unavailability, identify the principal root causes, and evaluate the results of the post-improvement condition using key performance indicators.

The literature supports the use of Lean and Six Sigma methodologies for identifying operational waste, improving flow, and reducing variability in regulated manufacturing environments. Lean principles such as visual management and point-of-use organization improve resource accessibility and reduce non-value-added activity [1] [2]. In addition, Six Sigma and SMED concepts support the systematic reduction of operational inefficiencies and downtime associated with process support resources [3]. Previous studies also indicate that the integration of Lean and Six Sigma provides an effective framework for improving performance while maintaining process control in medical device manufacturing environments [4]. However, limited research has focused specifically on fixture availability as a primary source of operational inefficiency. Inadequate fixture management can contribute to production delays and inefficiencies that are often overlooked in traditional capacity planning models [5], which further supports the relevance of this project.

METHODOLOGY

This project followed an applied, non-experimental, observational, and retrospective research design. The study was applied because it addressed a real operational problem in a manufacturing setting, and it was non-experimental because the researcher did not manipulate variables in a controlled environment. Instead, the work relied on the observation and analysis of existing process conditions and operational data. The retrospective nature of the study was based on the use of historical production information, downtime records, and documentation associated with fixture usage and control.

The research adopted a quantitative process-improvement approach supported by Lean Manufacturing and Six Sigma methodologies. The project focused on analyzing fixture-related downtime, interruption frequency, and fixture availability at the point of use. Lean principles guided the identification of waste, poor flow conditions, and visibility issues, while Six Sigma tools supported the statistical comparison of performance metrics between the baseline and post-improvement conditions.

Data collection included four principal methods: review of historical production downtime records related to fixtures, analysis of fixture usage logs and availability records, direct observation of fixture flow and handling practices on the production floor, and review of standard operating procedures related to fixture management. All data used in this study were obtained from the actual manufacturing environment in which the project was conducted. To protect confidential and proprietary company information, the data were analyzed and reported in aggregated form and used exclusively for academic purposes.

The independent variables considered in the study were fixture flow and layout configuration, fixture storage and availability practices, visual management and organization methods, and standard work related to fixture handling. The dependent variables were fixture availability percentage, production downtime related to fixture unavailability, frequency of production interruptions, and process consistency. A non-probabilistic, purposive sampling method was used because the study focused on specific lines, fixtures, and downtime events directly related to the identified problem.

The analysis plan included descriptive statistics, Pareto analysis, boxplot comparison, normality testing, and inferential statistical comparison of pre- and post-improvement performance metrics. These methods were selected to quantify process behavior, prioritize root causes, and evaluate whether the post-improvement condition outperformed the baseline condition.

RESULTS AND DISCUSSION

The baseline review confirmed that fixture-related downtime represented a recurring operational issue in the selected manufacturing area. Recorded interruptions associated with missing fixtures, misplaced fixtures, and delayed return of fixtures affected process continuity and produced avoidable delays. Although individual events were not always large in isolation, their repeated occurrence created cumulative impact on workflow continuity and response time.

A Pareto analysis was used to prioritize the recorded fixture-related causes. The results in Figure 1 showed that missing fixtures, misplaced fixtures, and waiting for fixture return represented the most frequent categories and together accounted for 61.5% of the total recorded events. This finding supported the prioritization of these categories during the root cause analysis stage and indicated that the majority of the problem was concentrated in a limited number of recurring operational failures. The recorded fixture-related defect/causes categories were missing fixture, misplaced fixture, waiting for fixture return, damaged fixture, no visual identification, and storage location not standardized.

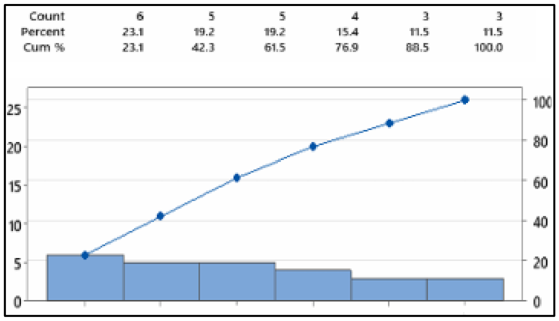

Figure 1
Pareto Chart of Fixture-Related Causes

The review of fixture usage and availability records revealed that fixture availability at the point of use was not consistently aligned with production needs. Operators frequently had to search for fixtures, wait for their return, or interrupt their work until the required fixture became available. The records also indicated limited visibility regarding fixture location and status, which weakened process control and increased dependency on informal coordination.

Descriptive statistics were calculated for the selected key performance indicators in both the baseline and post-improvement periods.

- The mean fixture-related downtime decreased from 37.53 minutes in the baseline period to 13.53 minutes in the post-improvement period, representing an approximate reduction of 63.9%.
- The mean number of interruptions decreased from 4.40 to 1.73, representing an approximate reduction of 60.7%.
- In contrast, fixture availability at the point of use increased from 80.93% to 95.00%, representing an improvement of 14.07 percentage points.

In addition to better average performance, the post-improvement period also showed lower variability for all selected KPIs, indicating greater consistency. These results are summarized in Table 1 and show clear differences between the baseline and post-improvement conditions.

Table 1
Descriptive Statistics

Statistics

Variable	Period	N	N*	Mean	SE Mean	StDev	Minimum	Q1	Median	Q3	Maximum
Downtime_Minutes	After	15	0	13.5333	0.838744	3.24844	8	11	14	16	19
	Before	15	0	37.5333	1.58525	6.13964	28	32	38	42	48
Interruptions	After	15	0	1.73333	0.181703	0.703732	1	1	2	2	3
	Before	15	0	4.4	0.254484	0.985611	3	4	4	5	6
Fixture_Availability_Pct	After	15	0	95	0.436436	1.69031	92	94	95	96	98
	Before	15	0	80.9333	0.752562	2.91466	76	79	81	83	86

Direct observations of the current state showed that fixture storage and handling practices were not fully standardized. Operators often relied on memory, experience, or informal communication to identify fixture location and status. In several cases, fixture retrieval required additional walking, searching, and waiting. These conditions contributed to motion waste, waiting waste, and poor point-of-use accessibility. From a Lean perspective, the current state did not support a stable and efficient flow of support resources through the production area.

The process mapping and current-state analysis showed that the movement of fixtures through the work area contained weak control points and several opportunities for inefficiency. Instead of providing clear and immediate fixture access, the process depended on repeated interaction with storage areas, shared resources, and informal practices. This reduced process responsiveness and made interruptions more likely during normal production conditions.

The root cause analysis suggested that fixture-related downtime was not caused by a single isolated factor. Instead, the problem reflected the interaction of several operational weaknesses, including inconsistent control methods, lack of standardized storage practices, insufficient point-of-use organization, limited visual management, and inefficient flow conditions. The prioritization of missing fixtures, misplaced fixtures, and waiting for fixture return was consistent with these broader root causes because all three reflected deficiencies in visibility, storage discipline, and return control.

Graphical comparison of the KPIs confirmed the separation between the baseline and post-improvement periods. Boxplots in Figure 2, Figure 3, and Figure 4 show that downtime minutes were substantially lower after the improvement period, interruption counts were shifted to a lower range, and fixture availability values were concentrated at a higher level. These visual results supported the interpretation that the process did not only improve in average terms, but also became more stable and more consistent.

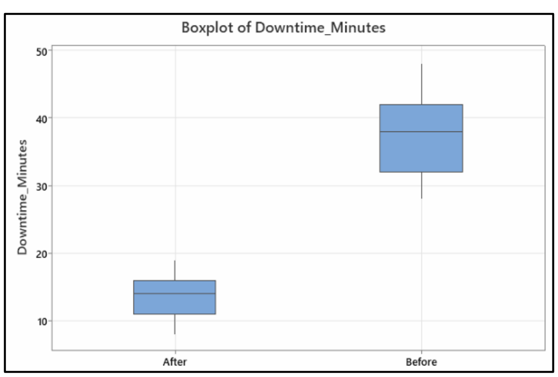

Figure 2
Downtime Minutes by Period

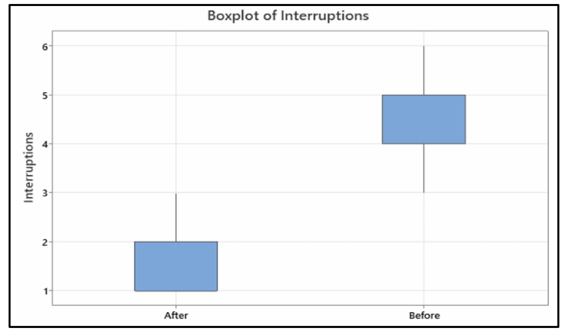

Figure 3
Interruptions by Period

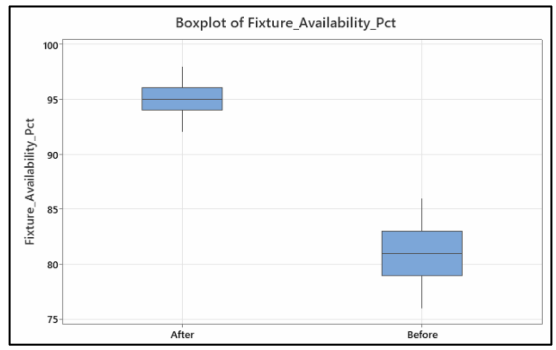

Figure 4
Fixture Availability by Period

These preliminary findings suggest that the improvement actions produced a meaningful operational effect. The reduction in downtime and interruptions, together with the increase in fixture availability, indicates that the process operated with better control, faster fixture access, and fewer workflow disruptions. Overall, the intervention improved both efficiency and day-to-day process stability.

Before selecting inferential tests, normality testing was performed using the Anderson-Darling method. Downtime minutes and fixture availability percentage did not show evidence against normality in either period and were therefore evaluated using two-sample t-tests. In contrast, interruption data in the post-improvement period did not follow a normal distribution, so interruptions were evaluated using the Mann-Whitney test.

- The two-sample t-test for downtime minutes showed a statistically significant mean reduction of 24.00 minutes, with a 95% confidence interval of -27.73 to -20.27 and a p-value below 0.001.

- The two-sample t-test for fixture availability percentage showed a statistically significant increase of 14.067 percentage points, with a 95% confidence interval of 12.262 to 15.871 and a p-value below 0.001.
- The Mann-Whitney test also showed a statistically significant reduction in interruption frequency, with the median decreasing from 4 in the baseline period to 2 in the post-improvement period and a p-value below 0.001.

These inferential results provide statistical support for the observed improvement in the selected key performance indicators.

Overall, the statistical and graphical analyses consistently indicated that the post-improvement condition outperformed the baseline condition across all selected KPIs. The reduction in downtime and interruptions, together with the increase in fixture availability, supported the interpretation that the process became both more efficient and more stable after the improvement period.

These results indicate that the improvement actions were associated with measurable gains in process performance. The reduction in downtime and interruptions, together with the increase in fixture availability, suggests that the revised fixture management approach improved point-of-use access, reduced workflow disruption, and supported a more stable operating condition. From a manufacturing engineering perspective, these outcomes are consistent with the expected effects of stronger visual control, better fixture flow, and improved standardization.

CONCLUSIONS

This project confirmed that fixture availability represented a significant operational factor in the continuity and efficiency of the selected manufacturing process. Fixture-related downtime and interruptions were associated with recurring weaknesses in fixture control, storage practices, flow organization, and point-of-use accessibility. Therefore, the problem identified in the original proposal was validated as a relevant manufacturing issue.

The quantitative results showed clear improvement between the baseline and post-improvement conditions. Mean fixture-related downtime decreased from 37.53 minutes to 13.53 minutes, mean interruption frequency decreased from 4.40 to 1.73, and fixture availability at the point of use increased from 80.93% to 95.00%. These results indicated that the post-improvement condition was associated with lower operational disruption, better accessibility of support resources, and improved process consistency.

The findings also showed that the fixture management problem extended beyond simple fixture shortage. The way in which fixtures were stored, moved, retrieved, and controlled within the work area had a direct influence on waiting time, downtime, and process stability. For this reason, a more structured fixture management strategy was necessary to reduce operational waste and improve performance.

Another important conclusion was that Lean and Six Sigma tools provided an effective framework for understanding and organizing the problem. The use of Pareto analysis, descriptive statistics, boxplots, normality testing, and inferential statistics helped transform a recurring operational issue into a structured engineering problem supported by data. This strengthened both the technical value and the practical usefulness of the project.

The study was subject to several limitations, including the detail and availability of historical data, the limited time frame available for analysis, and the focus on a single manufacturing environment. Even so, these limitations do not invalidate the results; rather, they should be considered when interpreting the results and when planning future validation or broader implementation efforts.

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