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

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Abstract

This design project addressed production fixture unavailability in a medical device manufacturing line, where missing, misplaced, or delayed fixtures generated avoidable downtime and process interruptions. The objective was to improve fixture availability and reduce fixture-related downtime through Lean and Six Sigma principles. The methodology used historical downtime records, fixture usage logs, direct observations, process mapping, cause-and-effect analysis, and statistical evaluation of key performance indicators. Results showed that missing fixtures, misplaced fixtures, and waiting for fixture return were the most frequent baseline causes. After improvement, downtime and interruptions decreased while fixture availability increased. The findings support that a structured fixture management strategy can improve operational efficiency and process stability.

Introduction

In medical device manufacturing, production fixtures are critical support elements because they help ensure consistency, repeatability, and process control during manufacturing activities. When fixtures are missing, misplaced, delayed, or unavailable at the point of use, the production flow is interrupted and operational performance is affected. This project focused on improving fixture availability in order to reduce avoidable downtime, improve workflow stability, and support better production efficiency.

Background

Lean and Six Sigma methodologies provide a structured framework for identifying waste, improving flow, and reducing process variation in manufacturing environments [1], [4].

- Lean principles such as visual management, point-of-use organization, and standard work support better fixture visibility and accessibility [2].
- Six Sigma tools help evaluate process performance using data, root cause analysis, and statistical comparison of baseline and post-improvement conditions [3], [5] .

Problem & Objective

PROBLEM

- Fixture availability at the point of use was inconsistent.
- Operators searched, waited, borrowed fixtures, interrupted work.
- This caused downtime, variability, and reduced productivity.

OBJECTIVE

- Improve production fixture availability to 95%.
- Reduce fixture-related downtime by at least 20%.
- Apply Lean and Six Sigma tools to create a sustainable fixture control system.

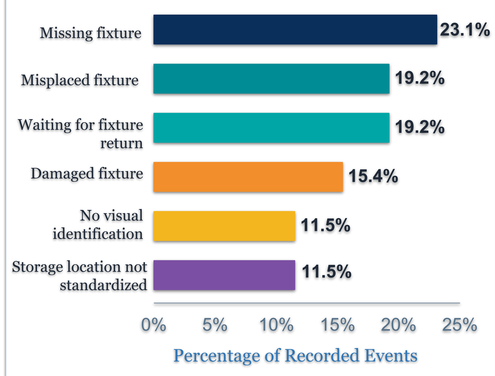
Methodology

1. Review historical downtime records
2. Analyze fixture usage and availability logs
3. Observe fixture flow, storage, and handling
4. Map the current process
5. Identify Root Causes with Lean / Six Sigma
6. Compare baseline vs. post-improvements KPIs

Research design: applied, non-experimental, observational, retrospective.

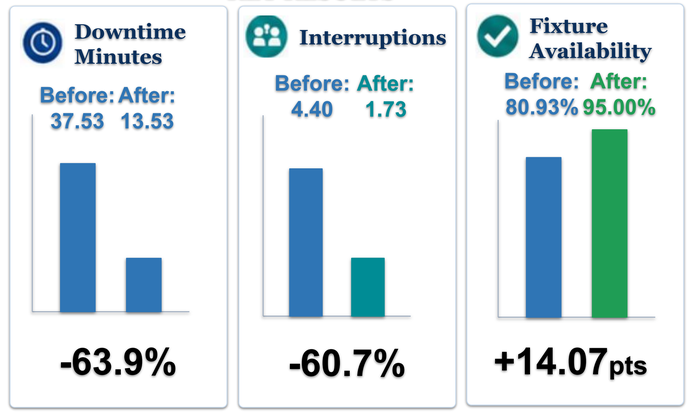
Results and Discussion

BASELINE CAUSES



The Pareto analysis showed that the top three fixture-related causes represented **61.5%** of the recorded events.

KEY RESULTS



Statistical Support

Downtime minutes: Two-sample t-test, $p < 0.001$

Interruptions: Mann-Whitney test, $p < 0.001$

Fixture availability: Two-sample t-test, $p < 0.001$

Post-improvement condition outperformed baseline across all selected KPIs.

Improvement Strategy

Visual Controls
Clearly identify fixture status and location.

Point-of-Use
Keep fixtures available where operators need them.

Standard Work
Define handling, return, and escalation practices.

KPI Monitoring
Track downtime, interruptions, and availability.

Main idea: make fixture flow visible, standardized, and measurable so operators spend less time searching and waiting.

Conclusions

The results showed that the fixture availability issue extended beyond fixture quantity. It was also a process flow, visibility, storage discipline, and control problem. After the improvement period, the process showed lower downtime, fewer interruptions, higher fixture availability, and improved process consistency. Fixture availability was a significant operational factor affecting production continuity and efficiency. A structured fixture management approach reduced downtime and interruptions. Lean and Six Sigma tools provided an effective framework for analyzing the problem and evaluating improvement. The post-improvement process became more efficient, stable, and easier to control. The quantitative results support that improving fixture visibility, point-of-use access, and standard work can strengthen manufacturing performance.

Future Work

- Expand the fixture management system to additional production lines.
- Strengthen visual controls and standardized fixture return practices.
- Continue monitoring KPI performance to confirm long-term sustainment.
- Evaluate whether similar fixture-related issues exist in other manufacturing areas.

References

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