



Abstract

The Johnson & Johnson Vision plant in Añasco manufactures Non-Toric intraocular lenses (IOLs), which have recently experienced a recurring issue of unintended fiducial markings. These defects, if undetected, compromise product integrity, patient safety, and production efficiency. Root cause analysis determined human errors specifically incorrect machine programming selection as the primary contributor. To address this, an upgraded version of CNC Program Assembler software was developed to enforce correct program usage through barcode scanning, preventing operational oversights. Complementary procedural actions included operator training, standard operating procedure updates, and engineering test validations. A cost benefit analysis revealed substantial material and labor losses due to incorrect production, justifying the proposed corrective measures. The revised system enhances traceability, reduces waste, and ensures consistent quality. Ongoing monitoring and feedback collection are planned to ensure sustainable improvements and compliance. This initiative reflects a strategic integration of risk management, process optimization, and quality assurance to support continuous improvement.

Introduction

The J&J Vision (JJSV) plant in Añasco manufactures Intraocular Optic Lenses (IOLs), including Toric and Non-Toric types. An escalation involving four complaints about unintended fiducial markings on Non-Toric lenses raised concerns about patient safety and operational disruptions. Each production order can include up to 432 units, increasing potential impact. The project aimed to determine whether the defects were due to equipment, process gaps, or human error. By optimizing the milling machine processing station, JJSV sought to enhance quality compliance, improve production efficiency, and prevent recurrence, aligning with its commitment to safety, integrity, and continuous improvement.

Literature Review

Manufacturing defects in intraocular lenses (IOLs), particularly unintended fiducial markings, pose significant risks to product quality and patient safety. Prior studies have emphasized the importance of proper machine calibration and predictive maintenance in reducing deviations during CNC milling operations [1]. Process mapping and gap analysis have been shown to help identify weaknesses in standard operating procedures (SOPs), while the use of Statistical Process Control (SPC) supports real-time process monitoring to detect anomalies early [2][3]. Additionally, research highlights human error as a frequent cause of defects in medical device manufacturing, often due to inadequate training or procedural missteps [4]. Implementing cross-functional collaboration and continuous improvement strategies has demonstrated a reduction in such errors. Furthermore, Failure Mode and Effects Analysis (FMEA) has proven effective in systematically identifying and mitigating process risks [5]. These findings collectively establish a robust foundation for developing corrective actions aimed at enhancing process reliability, traceability, and compliance in IOL production.

Methodology

Data Collection and Trend Analysis

The first phase involved collecting production data from the ALMAC milling station, where the fiducial markings were generated. A statistical trend analysis and a time study were conducted to assess the impact of errors on production efficiency and to quantify the material and labor losses associated with defective batches. The cycle times for Non-Toric and Toric lenses were measured—45 seconds and 1 minute 10 seconds respectively. In erroneous scenarios, the cycle time increased by a factor of 2.44, highlighting significant inefficiencies.

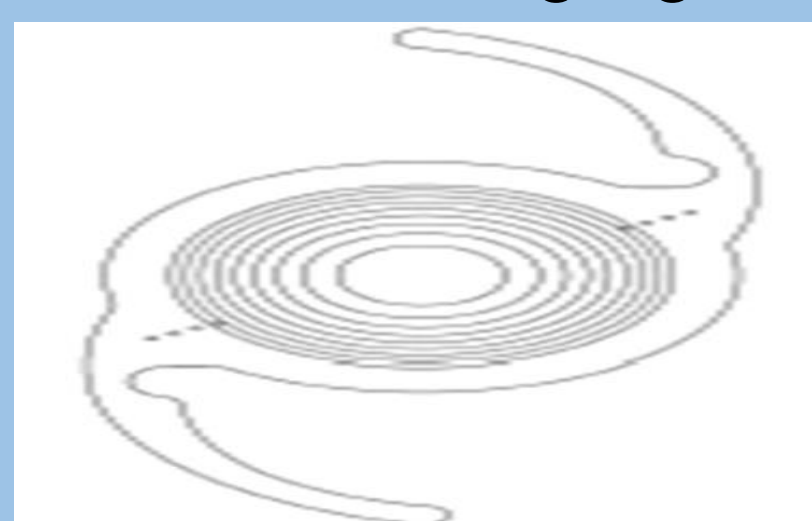


Figure 1: Toric Lens

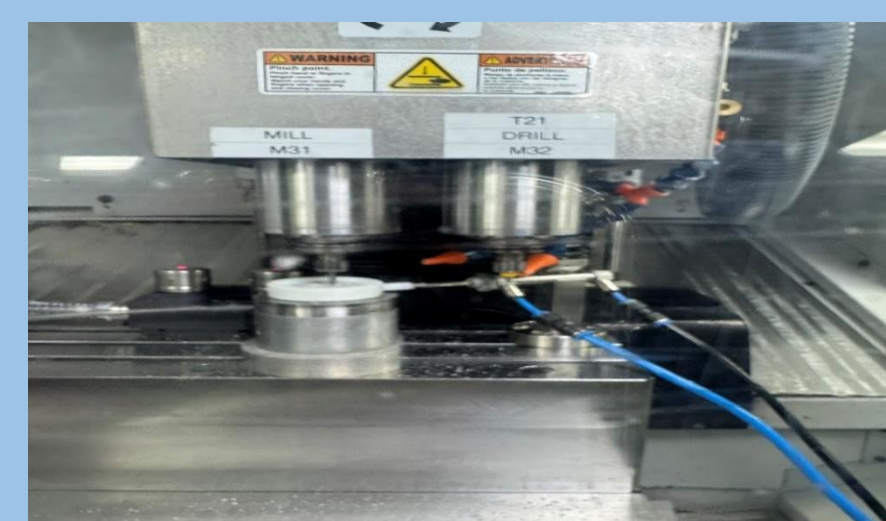


Figure 2: Milling Machine

Process Mapping and Gap Identification

A detailed process mapping was performed to understand the lens manufacturing workflow, from raw material intake to final inspection. It was established that only the ALMAC milling machine was involved in generating fiducial markings, and only for Toric lenses. According to the Lens Generation Manual Instruction MI944, operators were responsible for selecting the appropriate milling program—Program 051 for Non-Toric and Program 091 for Toric lenses. The latter required barcode scanning of production orders to download model-specific coordinates from the SAP system.

Operator interviews and SOP reviews revealed inconsistencies in program selection. Operators occasionally failed to switch from Program 091 to Program 051 when transitioning from Toric to Non-Toric orders, causing the machine to execute the last loaded program and apply unintended fiducial markings to Non-Toric lenses.

Root Cause Analysis

Root cause analysis confirmed that the defect stemmed from human error rather than equipment malfunction or software bugs. The failure to switch programs was attributed to oversight and lack of an automated verification system. Although post-milling inspections typically caught the defects, the resulting scrap and time loss were substantial.

Corrective and Preventive Actions (CAPA)

To resolve the issue, both technical and procedural CAPAs were introduced. Technically, a prototype CNC Program Assembler version 1.4 was developed to replace version 1.3.

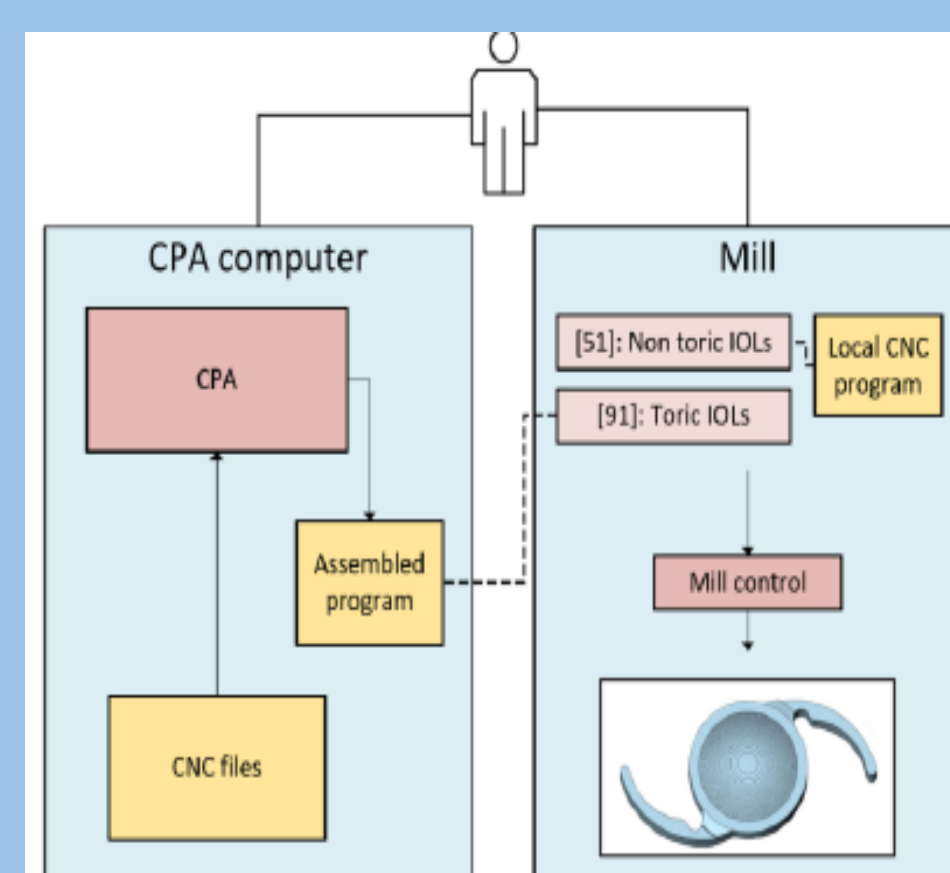


Figure 3: Program Assembler version 1.3

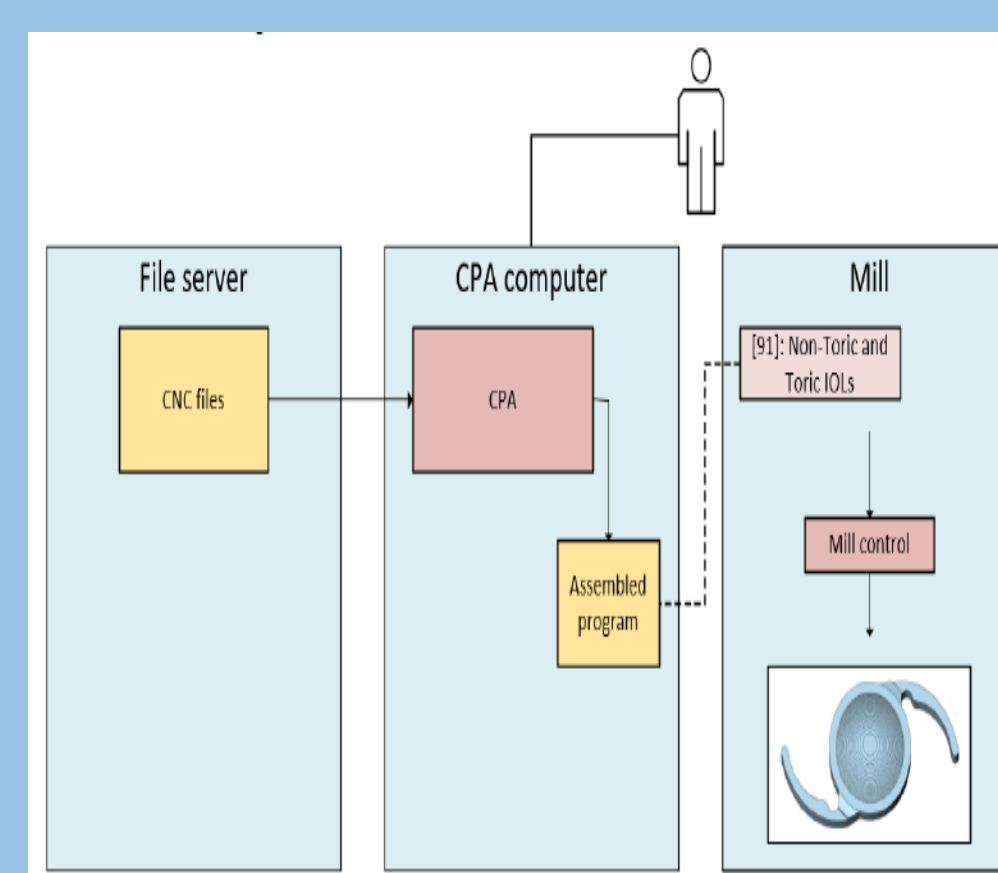


Figure 4: Program Assembler version 1.4

The new version allowed barcode scanning for both Toric and Non-Toric orders and restricted production to the exact quantity specified in the scanned order. This ensured correct program usage and improved traceability. Procedurally, all operators received targeted Awareness Training to reinforce the importance of correct program selection and order verification. The Manual Instruction MI944 was revised to reflect software changes and guide operators based on the version installed at their workstations.

Validation and Monitoring

Validation of the updated software was conducted through Engineering Test Protocols to ensure proper functionality under production conditions. Following successful testing, the software was rolled out across relevant lines. A six-month post-implementation monitoring period was established, incorporating KPIs for software usability, operator compliance, and defect tracking. Predictive maintenance and real-time monitoring systems were also implemented to ensure ongoing process reliability and continuous improvement.

Results

The results of this research confirmed that unintended fiducial markings on Non-Toric intraocular lenses were primarily caused by operator error during the selection of CNC milling programs. Statistical trend analysis and time studies demonstrated the substantial impact of these errors on manufacturing efficiency and resource utilization. Under correct production conditions, the average cycle time for Non-Toric lenses was 45 seconds. However, when an erroneous program was used, cycle times increased by a factor of 2.44, and entire batches were rendered defective. Table 1 illustrated that for a batch of 432 units, this translated to 7.8 hours of additional production time and full material scrapping.

Table 1: Summary of impact

Quantity	Correct Time (hrs)	Error Time (hrs)	Extra Time (hrs)	Scrap Units
72	0.9	2.2	+1.3	72
144	1.8	4.4	+2.6	144
216	2.7	6.6	+3.9	216
288	3.6	8.8	+5.2	288
360	4.5	11.0	+6.5	360
432	5.4	13.2	+7.8	432

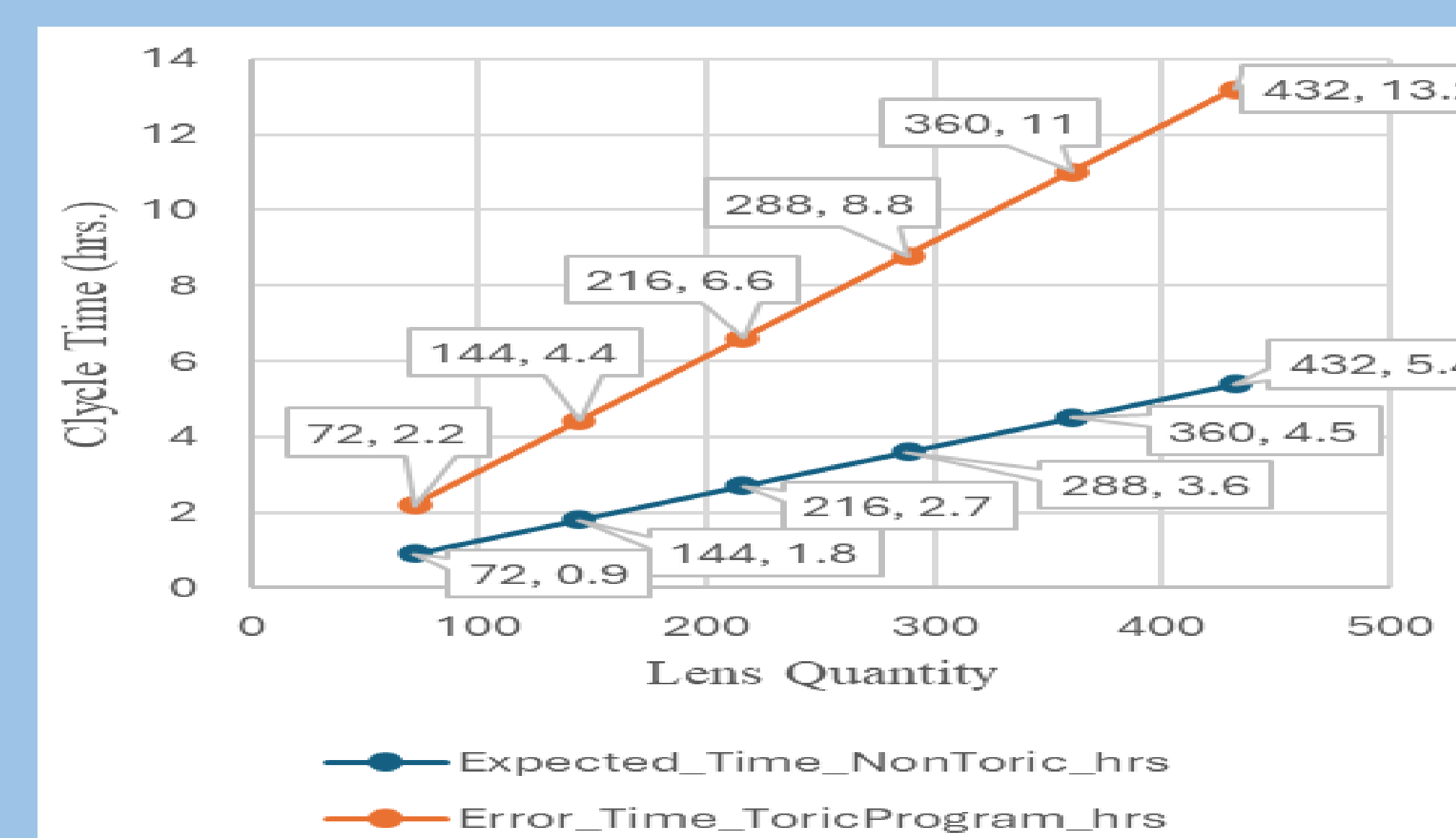


Figure 5: Time comparison of correct vs incorrect production order execution

Results

The implementation of CNC Program Assembler version 1.4, which enforced barcode scanning for all orders and restricted production to scanned quantities, significantly reduced operational errors. Engineering validation confirmed the software's functionality in real-time production environments. Cost-benefit analysis revealed a material and labor loss of \$1,043.57 per hour under incorrect production, justifying the need for corrective actions.

Conclusions

This research successfully addressed the issue of unintended fiducial markings on Non-Toric intraocular lenses at the Johnson & Johnson Vision Añasco plant by identifying human error in machine program selection as the primary root cause. Through root cause analysis, software upgrades, and procedural enhancements, the project significantly improved production accuracy, reduced material waste, and enhanced patient safety. The implementation of CNC Program Assembler version 1.4 enabled barcode-enforced program validation, eliminating manual selection errors and improving traceability. Operator training and updated standard operating procedures reinforced proper usage and compliance. Time studies and cost analyses demonstrated that incorrect production had considerable operational and financial impacts, validating the need for corrective actions. Post-implementation monitoring confirmed a reduction in errors and improved user experience. This project contributes a scalable and cost-effective solution to enhance quality assurance and operational reliability in medical device manufacturing, while promoting a sustainable approach to risk management and continuous improvement.

References

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- [2] Kumar, N., & Patel, R. (2021). "Process Mapping and Gap Analysis for Quality Improvement in Medical Device Manufacturing." *International Journal of Production Research*, 59(12), 890-905.
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