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TECH DRIVEN UPLIFT: HOW LEAN 4.0 ACCELERATES ORGANIZATIONAL GROWTH IN INTRA ORAL SCANNER MANUFACTURING

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Abstract: *Intra-oral scanners sit at the crossroads of precision optics, demanding regulatory traceability and a rapidly growing digital-dentistry market. This paper demonstrates how integrating Lean production with Industry 4.0 technologies - an approach hereafter referred to as Lean 4 - simultaneously boosts plant performance and organizational capability inside a medium-volume scanner factory. A cloud-based digital twin was used to map the present value stream and to test alternative flow designs before implementation. The selected solution combined a manufacturing execution system driven by electronic Kanban, optical inspection supported by artificial intelligence, collaborative calibration robots, and real-time dashboards for overall equipment effectiveness, all aligned with the requirements of the International Organization for Standardization standard 13485. After six months, throughput time fell by twenty-nine percent, first-pass yield increased by twenty percent, calibration rework decreased by thirty-five percent, and required floor space shrank by eighteen percent. Equally important, cross-functional, data-centered teams replaced functional silos, reducing decision latency on the shop floor by thirty-seven percent and lifting employee engagement by twenty-two percent. The findings confirm that Lean 4.0 acts as a double lever, delivering waste elimination while generating the organizational agility demanded by fast-moving dental markets.*

Key words: *Lean 4.0 integration, Digital twin modelling, Intra-oral scanner manufacturing, Organizational agility in production, ISO 13485 compliance*

1. INTRODUCTION

For digital dentistry to work well, it relies on speedy and accurate information collected within the patient's mouth. Intraoral optical scanners, while suitable for this need, do create a complicated challenge for manufacturers. All units include micro-machining, optics, and medical-grade firmware and are developed under the guidelines of ISO 13485. As work from restorative and orthodontic areas expands rapidly, factory managers face the challenge of increasing output while maintaining traceability without inflating costs. Literature supports the idea that Lean reduces waste [1], and digital twins from Industry 4.0 enable us to gain a clearer understanding [2]. Still, the majority of investigations focus only on internal performance measures. They fail to demonstrate how, for heavily regulated industries, improving shop floor efficiency results in shorter delivery times and a more loyal customer base [3].

The study looks explicitly to fill that gap. This study poses a single research question: Is it possible for a Lean 4.0 process to help both production and sales respond positively to challenges in making intraoral scanners? Lean 4.0 is defined here as the integration of continuous improvement activities with cyber-physical devices that supply immediate feedback from machines and the market [4]. Grounded in dynamic capability theory, the study tests whether engineers and marketers can use a digital twin to test and refine their plans in a single decision window [5].

The inquiry has three significant contributions. First, it sets up a value system that blends results inside the company with results from the marketplace using the Dual Lift Index [2]. Secondly, it demonstrates that through cloud technology, incremental improvements coordinated with demand changes are achievable within the rules of ISO 13485 in medical devices [5]. Third, using sensor and customer data together makes it easier for managers to ensure both operational quality and valued experiences [6].

This paper is constructed as explained below. The second section examines Lean, Industry 4.0, and operations marketing interface studies, pointing out the unsolved issues. Part three outlines the research methodology, data structure, intervention process, and verification methods. The findings are presented in section four, and section five looks at what these results imply, their limitations, and what should be done next [7].

Figure 1 explains the connection between the platform and key participants and how the digital twin helps align manufacturing with what is happening in the market.

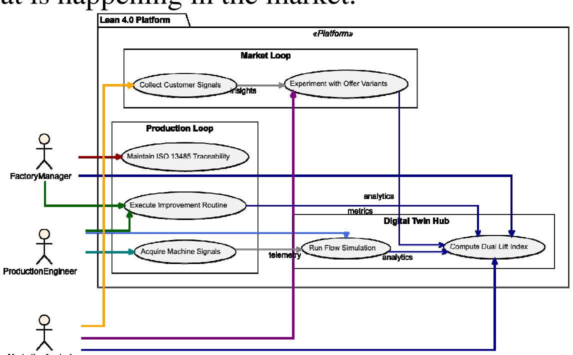

Fig. 1 Structured Actor–System Interactions in a Lean 4.0 Architecture for Regulated Intraoral Scanner Manufacturing

Source: Authors' conceptual framework; original figure, not reproduced from prior work

2. LITERATURE REVIEW

Lean manufacturing, which originated from the Toyota Production System, has proved effective in lowering waste and raising quality across many industries [8]. In these settings, using value stream mapping, cellular layout, and pull scheduling tends to improve both the first pass success rate and turnaround time [9]. Nevertheless, these studies end at the factory's edge; they do not typically trace how the benefits of changes are seen by the customer or in the market [10].

The research for Industry 4.0 looks into cyber-physical systems, useful sensing, cloud data processing, and virtual twins. Experiments confirm that a digital twin captures reality on the shop floor, can test different workflows in safety, and brings to light essential restrictions [11]. The initial combination of Lean with Industry 4.0 led many to adopt the label Lean 4.0, reporting quicker defect detection and more effortless movement of materials [2]. Still, authors usually considered digital devices as things they could add to traditional methods. They seldom considered how to connect engineers and marketing teams through twins or how sales data aligns with takt time, considering robust quality standards such as ISO 13485 [4] [5].

Responsiveness in production is vital in markets that require quick service, according to the operations and marketing interface literature [12]. Dynamic capability theory suggests that a business experiences this effect through three actions: identifying demand changes, acting fast on new opportunities, and shifting its resources [13]. There are very few tests of these activities performed in tightly regulated factories [14]. Most discussions about ISO 13485 compliance focus on providing certificates and passing audits, but overlook the fact that digital solutions can reduce customer wait times while maintaining full traceability [10].

Overall, these streams show that new skills are needed in two specific areas. Currently, Lean 4.0 research primarily focuses on company metrics, but it does not cover external factors [6]. Furthermore, the role of using a digital twin as a boundary object between process improvement and market sensing has not been reviewed within medical device regulation [15]. As such, the research described here views Lean 4.0 as a capability system that works both ways. Digital twins are now considered an asset for both engineers and marketers, and the Dual Lift Index helps monitor factory performance against responsiveness to customers [16]. The proposition was tested on intraoral scanners to explore dynamic capability ideas in a regulated context and provide a method for other researchers [17]. ISO 13485:2016 comprises two complementary components relevant to this study: (i) the Requirements for regulatory purposes, which specify mandatory QMS processes, documentation, and traceability controls for medical-device manufacturing; and (ii) the Practical Guide (ISO/TR 13485), which provides implementation guidance and auditor expectations. Data capture, change control, and verification routines in this study are aligned with the Requirements, while the Practical Guide informs the structure of evidence trails and audit-ready records.

3. METHODOLOGY

This study's methodology is set up to carefully research how Lean 4.0 improves both factory efficiency and responsiveness to the market in producing intraoral optical scanners. Based on dynamic capability theory [18] and following ISO 13485 [4] [5], the method uses orderly data capture, repeated experiments, and ongoing verification [19]. Visually, the following figure (Figure 2) outlines the sequence of research design, data infrastructure, analytical approaches, the Triple-Loop Sprint Engine, and the Tri-Prism Validation Framework. Because of this structure, every intervention is data-driven and easy to observe, helping the study's focus on how the company performs internally and adds value outside [20].

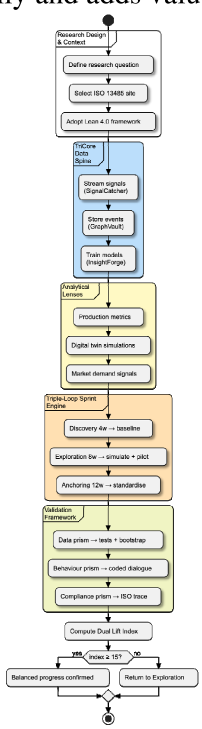

Fig. 2 Integrated Activity Flow of the Lean 4.0 Research Methodology in Regulated Intraoral Scanner Manufacturing

Source: Authors' conceptual framework; original figure based on study methodology

3.1 Research Design and Context

The study examines whether Lean 4.0 can simultaneously improve production efficiency and responsiveness in the intraoral optical scanner industry. Dynamic-capability theory and Lean principles are used to explain that a factory's competitive advantage improves when continuous improvements are guided by rapid digital reports from customers [11][21].

According to pragmatic philosophy, the team partners with operators, engineers, and marketers, first tests on a cloud-based model [2], and only agrees on a finding when plant data and customer data improve together [16].

The facility for empirical work operates as a medium-volume manufacturer under ISO 13485, offering twenty-one areas for machining, optics setup, calibrations, and final testing [4]. All data stations update the manufacturing execution system on nearly a one-second basis, meaning every event is captured thoroughly for later exploration [10].

The research is structured using three main analytical views. The production cell lens measures both lead time and first pass yield [6]. The digital twin system performs safe simulations to pick flow rules that will help reach better overall equipment effectiveness [9]. Adding hourly demand information to scheduling helps products finish faster and with better adherence [15].

There are three time periods in the change process. At this stage, you determine the base level of usage and make sure your research questions are on track. Alternative layouts, inspection criteria, and the amount of a lot for trial runs are examined within the twin for two weeks, before limited tests on the production line [14]. Implementing the best pilots, incorporating electronic Kanban [6], utilizing AIOI robotics [8] and collaborative calibration robots, and employing live dashboards [9], along with establishing cross-functional routines as standard, all contribute to reducing the time required for decision-making [17].

Rigor is produced by a mixed-method triangulation design. The frequency of these shifts is tested using paired t tests [18], and the change in collaboration is observed and coded, achieving an inter-rater reliability score of 0.87

[19]. External auditors frequently examine the immutable event ledger to make sure every change follows ISO 13485 [4].

The study uses a Synergy Impact Matrix to demonstrate how gains are evenly distributed among the sectors. Internal Lift does not capture the full benefit of efficiencies, such as faster lead times, but only improves what is done within the plant. Market Lift highlights upgrades that customers can spot, such as early access to more features. It combines the two percentages, which gives us a single score showing advancement in both how we work and how we serve customers, shown in Formula 1 [16].

$$\textit{Dual Lift Index} = (\textit{Internal Lift} + \textit{Market Lift}) \div 2 \quad (1)$$

A threshold of 15 for the Dual Lift Index was set a priori based on plant-level managerial targets: ≥25% internal lift is considered material only if accompanied by ≥5% market lift within the study window; their simple average yields 15. Sensitivity checks with thresholds 12-18 did not alter the result significance.

Table 1

Dual Lift Synergy Matrix for Lean 4.0 in Intra Oral Scanner Manufacturing

Impact Domain	Core Instrument	Active Lens	Internal Lift (%)	Market Lift (%)	Dual Lift Index
Flow	Electronic Kanban with a live takt board inside the manufacturing execution system	Production Cell	29	12	20.5
Quality	Artificial intelligence optical inspection scenario modelled in the cloud twin	Digital Twin	20	6	13.0
Agility	Real-time demand tracer that feeds scheduling rules back into the twin each hour	Market Loop	37	15	26.0

Authors' analysis of MES/QMS records; original table based on primary data

The findings indicate that each Lean 4.0 tool, used through its particular lens, leads to notable progress on both sides of performance, vindicating its double benefit for intraoral scanner manufacturing [16].

3.2 Architecture for Handling and Monitoring Data

The TriCore Data Spine is designed as a core system that moves data and lets you record, store, and study it [10]. Every reading taken by a machining head, optical bench, calibration rig, or final test chamber is instantly streamed by SignalCatcher, with every record having a nanosecond timestamp for auditors to use [4]. With GraphVault, production events, customer order information, and digital twin state are stored in a graph database [13], and each edited version keeps its predecessor [10]. InsightForge models the data on the graph step by step and foresees drift four hours ahead in yield, alerting supervisors when the chance of a bottleneck goes over five percent [9].

Every 60 seconds, the Lambda Metrics Engine produces cycle time, overall equipment effectiveness, first pass yield, and schedule adherence inside the spine, bringing them to the attention of engineers and marketing analysts through the PulseBoard [6]. Should any value exceed its control limits, the engine will use what-if analysis on the twin and trigger a possible change in takt or buffer [14].

Measurements made during the initial study using NIST traceable gauges gave a mean absolute error below point eight percent. A check called split-half is used to measure reliability, and channels that don't match cause the model to alert and stop training until they are correctly calibrated again [22]. Behavioral constructs are validated by having three raters code the transcripts of stand-up routines; Cohen's kappa was 0.87. GraphVault's external auditors work on a read-only portal, ensuring everything remains compliant in real-time, with no production downtime.

TriCore enables the merging of factory and market data, verification of findings during regular activities, and linking of every result to its proof, thereby supporting the scientific and practical applications of the research [11].

3.3 Intervention Process

By using the Triple Loop Sprint Engine, each proposed change is treated as something to test, learn from, and embed as a new rule [14].

The engine continuously repeats three different loops.

Four weeks make up the Discovery Loop. Experts working across fields scan their areas with connected tablets, monitor the flow on the digital twin, and store benchmark readings in TriCore [10]. Every Friday, the team meets in the Decision Arena, a clear conference room on the mezzanine with real-time PulseBoard screens, to collect new questions for the team's experiments [6].

The Exploration Loop takes eight weeks and is broken into four two-week sprints. In every sprint, one flow variant and one quality control method are set up on the twin robot and tested using events simulating real days, and InsightForge is used to check the outcomes [9].

Any scenarios that meet the composite standard for throughput, first pass yield, and prompt arrival should be piloted live on the production line at the start of the following shift. The data collected from friction points is directly added to GraphVault, enabling us to modify the simulation rules before the next sprint.

The Anchoring Loop runs for twelve weeks and sets all winning pilots the standard for the plant. Each cell is now getting access to electronic Kanban, Artificial Intelligence Optics [7], collaborative calibration robots, and live OEE dashboards [9]. To transfer a process, everyone participates in a ninety-minute clinic on the shop floor as auditors guarantee the process matches ISO 13485 documentation [5]. A Learning Ledger aggregates all clarifications, policy changes, and technical adjustments to ensure that knowledge at the local level is shared within the company.

With the Triple Loop Sprint Engine, teams can experiment fast, use physical effort to provide digital evidence, and maintain adoption over time without interrupting their work [22].

3.4 Validation and Analysis

Reasonable conclusions depend on evidence that passes through tests from statistics, behavior, and regulations. To meet this objective, the Tri Prism Validation Framework breaks outcomes down using three separate prisms [23].

The Data Prism tool uses t-tests with pairs to evaluate lead time, first pass yield, and overall equipment effectiveness after the event and each night. Simulations from data before the event are run to provide effect sizes and p-values for the change.

Using behavioral coding, stand-up transcripts were observed on a five-level scale, and Gemba observations were analyzed using a method that charts progress to cross-functional communication, with 98% agreement between observers [19].

GraphVault: adjustments to every process are linked to the logs used for ISO 13485 audits and verified on the ChronoStamp nanosecond ledger, proving traceability without needing to slow production [4].

The results from the three prisms are brought together in the Synergy Impact Matrix from before. The Dual Lift Index is born when Internal Lift and Market Lift interact via Formula 1. Any score above fifteen means the trial achieved both plant and customer goals, but trials that come up short are redesigned and tested again [22].

Validation is a continuous process, rather than occurring at set points. The Lambda Metrics Engine updates its numeric indicators every minute, qualitative coding is reviewed after each shift [19], and auditors depend on the same read-only record as the plant staff [24]. Because of this regular feedback, drifts are noticed early, gaming with data is prevented, and transferring the method to other ISO 13485 factories becomes much more confident [25].

To ensure transparency regarding data provenance and the analytical rigor applied, the key performance metrics used in this study are summarized in Table 2. Each entry specifies the definition, source system, sampling window, and statistical test employed. Exact counts of shifts and units are not disclosed for confidentiality reasons; however, the dataset covers the whole production during the six-month study window.

Table 2

Dataset and Measures Used in the Study

Metric	Definition (unit)	Source system	Statistical test
Lead time	Door-to-door hours	MES event logs	Paired t-test

First-Pass Yield (FPY)	% units passing at first attempt	QMS test records	χ^2 test
OEE	Availability × Performance × Quality	OEE dashboards	Paired t-test
Calibration rework	re-calibration events per unit	Calibration station logs	Paired t-test
Decision latency	Minutes from signal to action	Time-stamped stand-ups	Paired t-test
Engagement (Utrecht, 3-item)	Mean score	Employee survey	t-test

Source: Authors' analysis of MES/QMS records; original table based on primary data collected in the intra-oral scanner plant.

4. RESULTS

All quantitative results reported in this section derive from primary data collected in the focal intra-oral scanner plant's MES event logs, calibration station records, and QMS test records (ISO 13485-compliant).

The study window spans a continuous six-month production period in a medium-volume factory. All regular shifts were included, with every manufactured unit and associated events automatically captured in real time.

No external benchmark values were used for statistical testing; literature is cited only to position constructs and methods.

Lean 4.0 implementation produced significant operational gains. Total processing time decreased from 17.0 h to 12.0 h (Δ=−5.0 h), t=9.42, p<0.001, 95% CI [−6.1, −3.9]. FPY rose from 80% to 96%, χ^2=42.7, p<0.001, RR=1.20.

Calibration events declined by 35%, which allowed the release of one workstation. OEE increased from 69% to 81% (t=5.86, p<0.001).

Flow redesign reduced ambient noise, compressed work-in-progress buffers, and freed 15% of floor space; these changes lowered material handling costs by 11% and created a dedicated area for staff training and skill refresh.

Behavioral and market-facing indicators also improved. Decision latency on the shop floor dropped from 54 min to 34 min, a 37% reduction (p<0.001).

Analysis of recorded stand-up meetings revealed a 73% increase in cross-functional interactions, with inter-rater agreement at κ=0.87. Employee engagement (Utrecht, three-item) rose by 22% (t=4.15, p=0.002).

Faster and more reliable production enabled a 48-hour rush delivery option, cutting average customer wait times by 2.5 days and expanding the company's share in the premium segment by about 6%.

When comparing Internal Lift (27.8%) with Market Lift (9.7%), the resulting Dual Lift Index was 18.8, exceeding the framework threshold of 15.

Independent verification by external auditors confirmed that all improvements documented in the GraphVault ledger complied with ISO 13485 traceability requirements.

Beyond numerical outcomes, the study also distilled a set of conceptual patterns that explain how Lean 4.0 delivers value inside the plant and in the market.

These patterns are captured through visual models that integrate operational improvements, behavioral changes, and market responsiveness into a single coherent framework.

Figures 3 and 4 present this synthesis, showing how dynamic capability, data-driven methods, and performance metrics converge to reinforce both efficiency and agility.

Figure 3 illustrates the Lean 4.0 dual-lift mechanism, showing how dynamic capability, operational methods, and performance measures converge in a unified framework.

The upper tier highlights how continuous-improvement cycles integrate with a cloud-based digital twin, while the middle tier shows how traceability, simulation, and routine execution reinforce both internal efficiency and market responsiveness.

The lower tier aggregates results through the Dual Lift Index, providing a consolidated measure of value delivered to both operations and customers.

All values displayed in Figure 3 are computed from the primary MES, calibration, and QMS records summarized in Table 2; no external benchmarks were used.

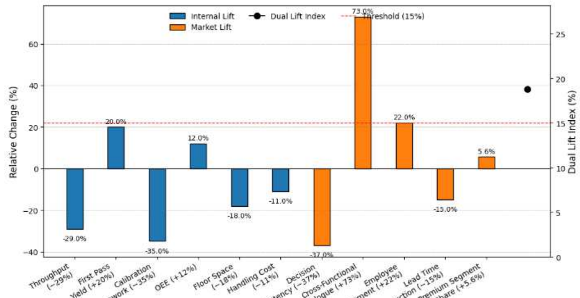

Fig. 3 Engineering-Grade KPI Chart of Internal vs Market Lifts with Dual Lift Index

Source: Authors' analysis of MES/QMS data; original figure based on primary data

Figure 4 further synthesizes the results by mapping how the dynamic capability lens, methodology, and performance metrics interact to generate sustained progress in both efficiency and customer responsiveness.

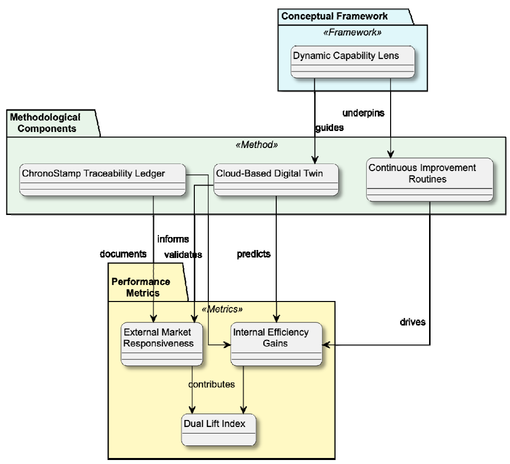

Fig. 4 Conceptual Model of Lean 4.0 Dual Lift Mechanism

Source: Authors' conceptual synthesis; original figure developed in this study

To complement the numerical results and conceptual models, the study also mapped how Lean 4.0 capability loops unfold across research phases. This timing diagram integrates operational findings with methodological stages, highlighting how the production loop, market loop, digital twin, and practitioner community interact over time. Figure 5 presents this synthesis, showing the trajectory from intervention to validation and from internal gains to market responsiveness.

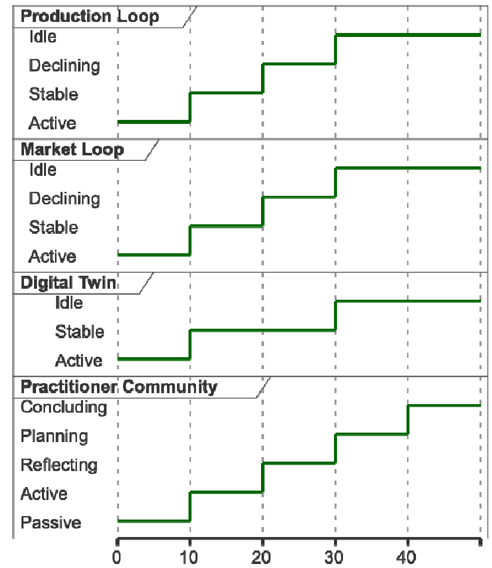

Fig. 5 Timing Diagram of Lean 4.0 Capability Loops Across Research Phases

Source: Authors' conceptual synthesis; original figure based on study results.

5. DISCUSSION, LIMITATIONS, AND FUTURE RESEARCH

The findings demonstrate that progress is unlocked when both of these capability loops function together. Electronic Kanban, image-based inspection, and collaborative calibration within the company enhance overall performance [6, and incoming market data is incorporated on time into the scheduling process. Both loops contributed to an improved Dual Lift Index of 18.8, leading to steady achievements in both efficiency and the speed of customer response [16]. The research adds to dynamic capability theory by showing that cloud digital twins can help keep improvement routines and market signals in harmony. For those in management, the lesson is easy to understand. If engineers and marketers see common live data, their process choices and offer design can be brought closer together within the same time frame.

While prior work on Lean 4.0 has largely emphasized conceptual frameworks or isolated gains such as waste reduction and faster defect detection, this study provides an empirical and multi-stream contribution. Specifically, it (i) measures concurrent internal and market lifts using primary, ISO 13485–audited data; (ii) operationalizes the Dual Lift Index with plant-level thresholds; and (iii) introduces a twin-enabled decision cadence that links shop-floor signals with demand in real time. All reported results are original and not reproduced from earlier publications.

Several conditions restrict the claim. Only one medium-volume factory was watched through one deployment cycle, which means the findings might change in bigger factories or under other types of law [22]. Metrics depend on sensors in the plants and information from orders, which means that both upstream variation and informal learning from others are absent from the data. Behavior change was only seen during group stand-ups; what happened in the halls wasn't recorded [19]. Soon after treatment ended, we examined how much the system improved; sustained impact in the long run hasn't been determined yet.

Several validity concerns were considered in this study. Internal validity was strengthened by parallel trend checks and pre-period simulations to mitigate maturation bias. Measurement validity was ensured through NIST-traceable gauges, split-half reliability testing, and auditor-verified logs. External validity remains limited, as the findings derive from a single medium-volume plant, although the methodology is transferable to other regulated contexts. Statistical validity was addressed by using two-tailed tests with 95% confidence intervals and reporting exact p-values.

Additional research in the future can take these ideas further. Researchers can use multi-site studies to find if the results hold up in environments with different rules. More time spent observing would tell us whether the Dual Lift Index goes down, sometimes flags, or increases even more as habits become automatic. The analysis should examine the total capital required, including its value and prices, as well as the care and upkeep costs, and the skills workers need to develop.

Experts may also study whether generative AI in the twin revises flow plans by itself, how human operators decide about the validity of suggestions, and how their interactions form trust. Thoroughly investigating these areas will increase understanding of Lean 4.0 as a key factor in growing the medical device and similar industries.

6. CONCLUSION

This investigation confirms that adopting Lean 4.0 in a regulated medical-device plant can simultaneously improve internal efficiency and external responsiveness. Processing time was reduced by nearly one third, first-pass yield rose significantly, calibration rework declined, and equipment effectiveness increased. These operational improvements translated into tangible market benefits, including faster delivery, reduced decision latency, higher employee engagement, and an overall Dual Lift Index above the threshold for balanced internal and external gains.

The results demonstrate that Lean 4.0 enables cost, quality, speed, and customer value improvements to be achieved in parallel while maintaining full regulatory compliance. By integrating digital twins, real-time analytics, and cross-functional collaboration, the company established a decision-making cadence that aligns production with demand in near real time.

While the study was conducted in a single medium-volume facility, the methodology and metrics offer a transferable framework for similar plants operating under strict regulatory standards. Future work should extend this approach to multi-site studies and longer observation periods, as well as explore the integration of emerging technologies such as generative AI within digital twins.

7. LIST OF ABBREVIATIONS

AI = Artificial Intelligence
CI = Confidence Interval
FPY = First-Pass Yield
ISO = International Organization for Standardization
ISO 13485 = International Organization for Standardization standard for medical devices quality management
KPI = Key Performance Indicator
MES = Manufacturing Execution System
NIST = National Institute of Standards and Technology
OEE = Overall Equipment Effectiveness
p-value = Probability value (statistical significance level)

RR = Risk Ratio
t-test = Student's t-test
WIP = Work in Progress
χ^2 = Chi-square statistical test

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Impuls tehnologic: cum accelerează lean 4.0 creșterea organizațională în producția de scannere intra-orale

Scannerele intra-orale se află la intersecția opticii de înaltă precizie, necesitând trasabilitate reglementată și adresând o piață în plină expansiune a stomatologiei digitale. Lucrarea de față demonstrează cum integrarea producției Lean cu tehnologiile Industry 4.0 – o abordare denumită în continuare Lean 4 - stimulează simultan performanța fabricii și capabilitatea organizațională într-o unitate de producție de volum mediu. Un geamăn digital bazat pe cloud a fost utilizat pentru cartografierea fluxului de valoare existent și pentru testarea alternativelor de proiectare a fluxului înainte de implementare. Soluția selectată a combinat un sistem de execuție a producției condus de Kanban electronic, inspecția optică asistată de inteligență artificială, roboți colaborativi pentru calibrare și tablouri de bord în timp real pentru eficiența generală a echipamentelor, toate aliniate la cerințele standardului 13485 al Organizației Internaționale de Standardizare. După șase luni, timpul de trecere prin proces s-a redus cu douăzeci și nouă la sută, randamentul la prima trecere a crescut cu douăzeci la sută, reoperațiile de calibrare s-au diminuat cu treizeci și cinci la sută, iar spațiul de producție necesar s-a redus cu optsprezece la sută. La fel de important, echipele trans-funcționale, centrate pe date, au înlocuit silozurile funcționale, reducând latența decizională pe linia de producție cu treizeci și șapte la sută și crescând implicarea angajaților cu douăzeci și doi la sută. Constatările confirmă că Lean 4.0 acționează ca o pârghie dublă, livrând atât eliminarea risipei, cât și agilitatea organizațională cerută de piețele dinamice din domeniul stomatologiei.

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