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Enhancing Supply Chain Efficiency in Bangladesh's Medical Device Manufacturing Industry Through Lean Tool Implementation

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Abstract

Lean methodology, widely recognized for its ability to optimize efficiency by reducing waste, has proven to be highly effective in supply chain and manufacturing environments, including medical device production. This study explores the application of lean tools, such as Kaizen, 5S, Root-Cause Analysis, and Kanban, within the medical equipment manufacturing sector, an industry under increasing pressure to enhance product quality, reduce costs, and ensure patient safety. Using qualitative research methods, including interviews and focus group discussions, the study examines how these tools are applied in practice and their impact on manufacturing processes. The findings indicate that lean practices can significantly improve operational efficiency, reduce defects, and enhance product quality, contributing to both cost savings and better healthcare outcomes. Despite challenges such as data confidentiality and a limited respondent pool, the results suggest that the careful implementation of lean tools is critical for navigating the complex regulatory landscape and driving continuous improvement. The study concludes that, when effectively adopted, lean principles can streamline operations, enhance competitiveness, and play a pivotal role in advancing healthcare quality as the industry evolves.

Keywords: Medical device supply chain, Lean tools, Focused group discussion, 5S Methodology, Root-cause analysis.

1 | Introduction

This study examines the implementation of lean tools within the medical device manufacturing supply chain to address persistent inefficiencies and enhance performance.

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The medical device sector plays a vital role in providing essential medical products globally. With rising demand, there is a pressing need to streamline operations while maintaining high standards of quality and cost-effectiveness.

Despite the adoption of modern management techniques, challenges such as overproduction, excess inventory, and inefficient resource allocation continue to affect the industry [1]. These issues lead to increased costs, reduced agility, and potential quality risks [2]. To address these problems, this research focuses on applying lean methodologies, including 5S for organizing and standardizing work environments, root-cause analysis to diagnose underlying process issues, and the PDCA (Plan-Do-Check-Act) cycle to drive ongoing improvement [3], [4].

The study explores how these lean tools can help eliminate waste, optimize processes, and improve productivity in the medical device supply chain [5], [6]. Lean principles, which originated in the Toyota Production System, are particularly relevant for addressing inefficiencies such as unnecessary transportation, excess inventory, and overproduction [7]. By implementing these principles, the study aims to enhance supply chain efficiency, reduce operational costs, and improve product quality [8], [9].

Additionally, the research investigates the impact of lean tools on key aspects such as supplier coordination, resource allocation, and overall supply chain management. It seeks to develop a comprehensive framework for applying lean tools in this context, ensuring regulatory compliance, and promoting a culture of continuous improvement.

Ultimately, this study aims to expand knowledge of lean manufacturing in the medical device industry, helping manufacturers achieve operational excellence, respond more effectively to market needs, and foster the industry's growth and sustainability.

2 | Research Background

The medical device manufacturing industry, which produces essential products such as diagnostic equipment and surgical instruments, faces challenges in optimizing supply chains to meet rising demand efficiently. Lean tools, which originated from Toyota's production system in the 1950s and focus on reducing waste and improving efficiency, offer solutions to these challenges [10].

Lean principles such as just-in-time production, continuous flow, pull systems, and total employee involvement are highly relevant to this sector. The medical device supply chain is complex and regulated, presenting issues such as inefficient processes, excess inventory, compliance risks, and coordination difficulties among suppliers. Applying lean tools can help address these issues by reducing waste, enhancing efficiency, and improving quality and collaboration [11].

In Bangladesh, the medical device manufacturing sector is experiencing growth and exploring lean tools to boost competitiveness and efficiency. Studies indicate that lean practices such as just-in-time manufacturing and the 5S methodology can reduce inventory costs, improve production efficiency, and create a safer work environment [12]. However, issues such as organizational resistance, insufficient expertise, and strict regulatory requirements continue to pose obstacles.

Successful implementation of lean tools in Bangladesh's medical device manufacturing industry requires overcoming these barriers through best practices, including top management commitment and employee involvement. Integrating lean principles with digital technologies can also enhance supply chain visibility and efficiency. Further research is needed to provide practical insights into effective lean adoption in this context, ultimately leading to improved operational performance and competitiveness [13], [14].

3 | Methodology

This research aims to explore the application of lean tools within the supply chains of medical device manufacturing industries using a mixed-methods approach [15], [16]. The study combines qualitative and

quantitative methods to provide a comprehensive understanding of lean integration and its effects on supply chain management.

3.1| Research Design

The research design is structured to identify and analyze the application of lean tools and their impact on Key Performance Indicators (KPIs) within the medical device manufacturing sector. The design will compare and contrast various aspects of lean tool application across different organizations [17].

I. Independent Variable: sector (Manufacturing).

II. Dependent Variables: application of lean tools and KPIs, including:

III. Cost Reduction: reduce operational costs by adopting lean methods.

IV. Lead Time Reduction: shortening of the supply chain process from order to delivery.

V. Inventory Management: optimization of inventory levels.

VI. Quality Improvement: enhancement of product/service quality.

VII. Customer Satisfaction: improvement in customer satisfaction resulting from lean practices.

This approach aims to offer insights into how lean tools are applied and their effects on supply chain management practices across various organizational contexts.

Research Hypotheses

For Research Question 1

Hypothesis 1. Lean tools reduce lead time and increase efficiency in the medical equipment manufacturing industry.

Hypothesis 2. Adopting lean tools in the medical equipment manufacturing industry improves product quality and reduces errors.

For Research Question 2

Hypothesis 3. Successful implementation of lean tools within the medical device manufacturing supply chain is positively associated with strong leadership support and commitment from top management.

Hypothesis 4. Adhering to regulatory guidelines for medical equipment standards is a major challenge in implementing lean tools [18].

3.2|Sampling

We'll select organizations like Company X and Company Y to ensure a diverse view of lean tool application across different manufacturing contexts.

3.3|Instruments

Qualitative phase

Managers, supply chain experts, and industry professionals will participate in detailed interviews. These interviews aim to uncover how lean tools are implemented, the challenges encountered, and the lessons learned [19].

Quantitative phase

Surveys will gather numerical data on the impact of lean tools on KPIs.

3.4|Analytical Tools

Qualitative analysis

Thematic analysis will be employed to review interview data and uncover recurring patterns and key insights.

Quantitative analysis

Statistical methods will be employed to analyze survey data and assess the effects of lean tools on performance metrics.

4| Data Analysis

4.1|Data Collection Framework for Focused Group Discussion

A framework was developed to collect data from the respondents. Data has been collected according to the following process [20]:

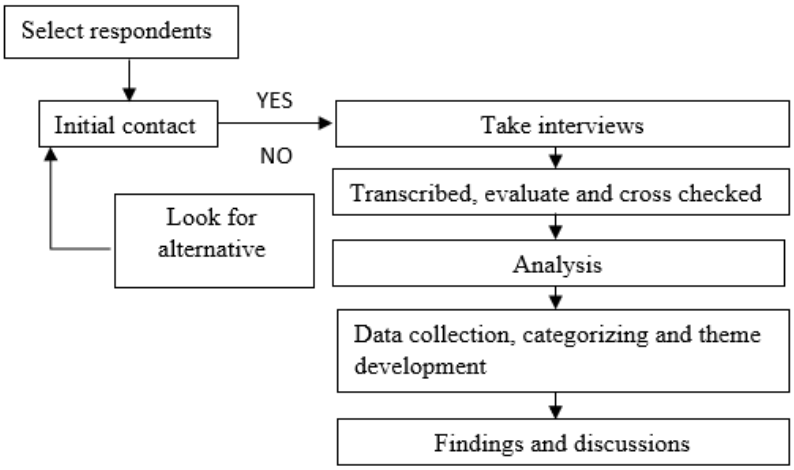

Fig. 1. Data collection framework for focus group discussion.

Table 1. Background of the respondents.

SI	Participants ID	Designation	Organization	Experience (Years)
1	A1	Executive, SCM	Company X	2
2	B1	Deputy Executive, QCI	Company X	9
3	C2	Deputy Manager, Engineering	Company X	10
4	D4	Sr. Executive, HR	Company X	5
5	F6	Executive, SCM	Company Y	2
6	G9	Executive, QCI	Company Y	3.5
7	X7	Deputy Manager, Engineering	Company Y	10

4.2|Research Questions and Themes

A few research questions were developed, and respondents were requested to answer them based on the given themes.

Table 2. Questions and themes.

Research Question	Identified Themes
RQ 1: How do the supply chain and lean tools work in the medical equipment manufacturing industry, and what is their impact on increasing efficiency and effectiveness?	Overall supply chain process and types of lean tools used Working Mechanism with Lean Tools
RQ 2: What are the key challenges and success factors in the implementation of lean tools within the medical device manufacturing supply chain?	Key challenges Success factors

5 | Data Analysis and Findings

Respondents answered the research questions based on the developed themes for both companies. The objectives of the research project are to determine how lean tools work in the medical equipment manufacturing industry.

5.1 | Company X (Global Pharmaceuticals)

Company X's supply chain includes upstream (managed by Supply Chain), midstream (handled by manufacturing), and downstream (overseen by Quality Control). Seven cross-functional teams work together to enhance customer satisfaction and improve the system.

5.1.1 | Overall supply chain process and types of lean tools used

Company X, which produces blood tubing sets for Kidney dialysis, aims to continuously improve its system and satisfy customers by applying various lean tools across all departments, from raw materials to end customers.

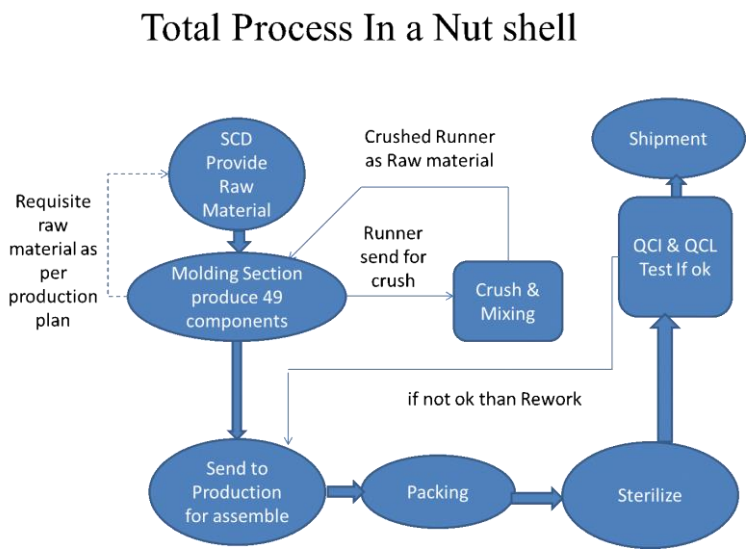

Fig. 2. Overall supply chain process of company X.

5.1.2 | Upstream

Supply chain team

Respondent A1 from Company X uses the Kanban method to improve their supply chain by managing raw materials, visualizing work processes, limiting work in progress, and boosting material flow, which helps ensure continuous production and smooth operations.

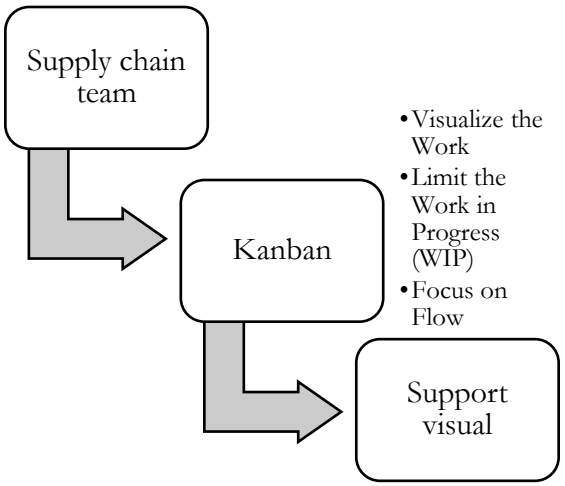

Fig. 3. Use of lean tool by supply chain team

5.1.3 | Midstream

Molding and extruder team

Respondent C2 outlined that the midstream section at Company X includes engineering, molding, and extruder teams with various machines. They use lean tools like 5S for cleanliness, Kaizen for improvement, Root-Cause Analysis for issues, and Poka-Yoke to prevent errors, ensuring quality and customer satisfaction.

Fig. 4. Use of lean tool by the injection molding & extruder team.

Production team

The Production team assembles components using lean tools such as JIT and 5S to reduce costs and waste. The Engineering team uses TPM to improve equipment efficiency and SMED to accelerate changeovers.

Fig. 5. Use of lean tool by production team.

Engineering team

The engineering team consists of the maintenance and utility team, which provides 24/7 support to production by delivering power, water, HVAC, and machine maintenance, including preventive and scheduled maintenance.

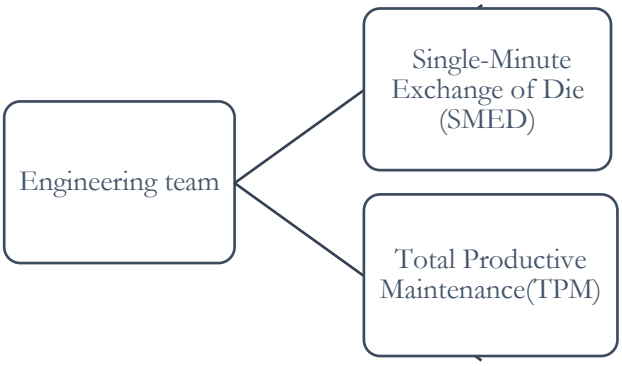

Fig. 6. Use of lean tool by the Engineering Team.

5.1.4 | Downstream

Sterilization team

C2 noted that the Sterilization team uses "HEIJUNKA" to ensure product quality, minimize costs, and reduce inventory. After sterilization, the QC team checks samples and approves them for shipment.

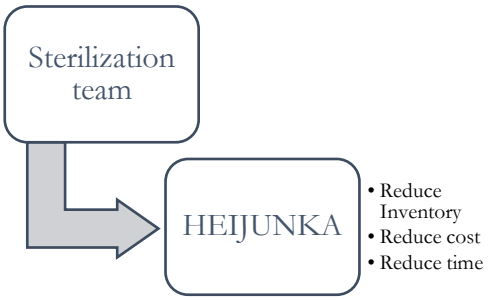

Fig. 7. Use of the lean tool by the Sterilization team.

5.1.5 | Working mechanism with lean tools

Company X uses quarterly Kaizen plans with the PDCA method, applies 5S to improve the environment, and Poka-Yoke to prevent errors. Gemba helps identify issues at their source. Root-cause analysis is frequently used, including why-why and fishbone methods, to address and prevent nonconformities.

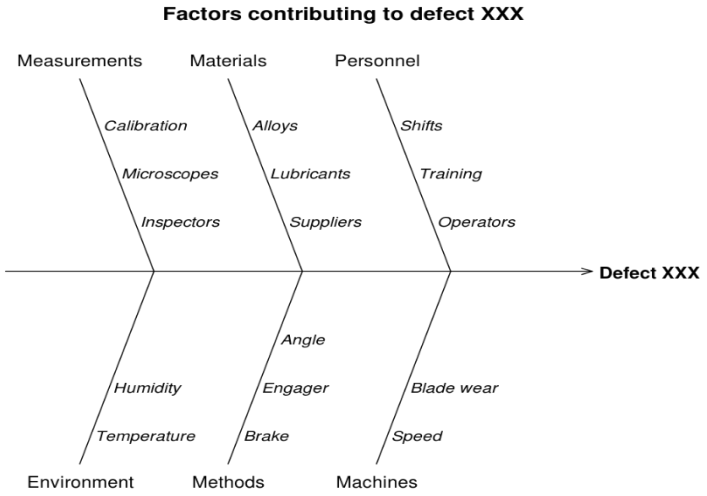

Fig. 8. Fishbone/Ishikawa diagram to identify root cause.

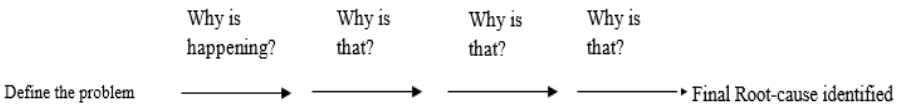

Fig. 9. Why -Why analysis to identify root cause.

5.2 | Company Y (Team Pharmaceuticals)

Respondent F6 from company Y stated they make syringes and drain bags for company X, sourcing materials from both company X and local suppliers. Their supply chain is split into three parts, each using lean tools.

5.2.1 | Overall supply chain process and types of lean tools used

Company Y makes syringe accessories and drain bags, sourcing raw materials from external suppliers. They sell 80% of the drain bags to company X and the rest locally.

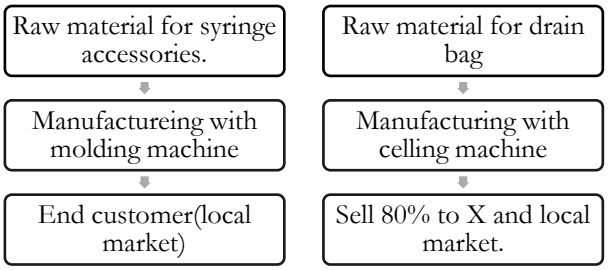

Fig. 10. Phase of SCM of company Y.

5.2.2 | Purchase and Manufacturing

The purchase and manufacturing teams at company Y use lean tools like Kaizen, 5S, Poka-Yoke, JIT, PDCA, and Continuous Flow to improve processes. The supply chain team sources raw materials from company X and uses Kanban for visual management, while the molding and production teams also apply these lean tools.

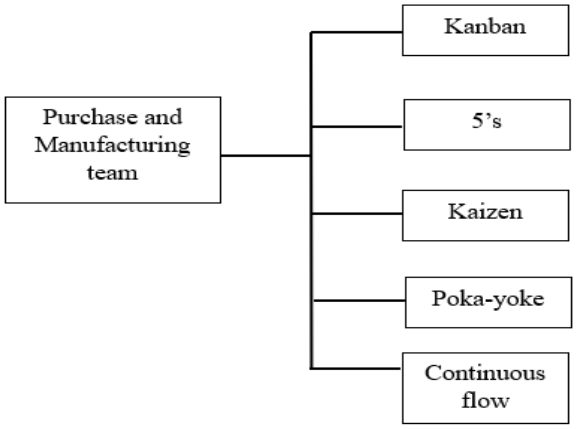

Fig. 11. Use of lean tools by the purchase and manufacturing team.

5.2.3 | Selling to the End customer

Respondent G9 from company Y mentioned using PDCA, Poka-Yoke, and Fishbone to improve their sales process. PDCA is used for projects, Continuous Flow ensures smooth operations, and root-cause analysis ensures quality. The Quality Compliance (QC) team checks samples post-manufacturing, uses lean tools for quality control, and supports national audits.

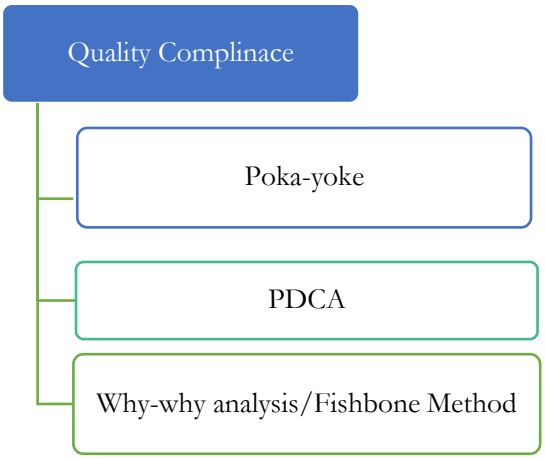

Fig. 12. Use of the lean tool by Quality Compliance Team

5.2.4 | Working Mechanism with Lean Tools

Company Y uses various lean tools to improve processes. The supply chain team uses Kanban to improve work visualization and streamline workflow. The manufacturing team uses 5S, Continuous Flow, Kaizen, and Poka-Yoke to enhance workplace efficiency and prevent issues. The QCI team employs root cause analysis and PDCA for quality control and project management.

Key challenges

By the statement of F6, G9, and X7, as they mentioned that the industry faces some challenges, such as –

I. Resistance to change.

II. Insufficient skills and knowledge.

III. Inadequate training.

Success factors

I. Use lean tools and methods.

II. Improve the overall process.

III. Waste minimization.

IV. Cost saving.

6 | Discussions

Global Pharmaceuticals employs more lean tools than Team Pharmaceuticals, leading to better outcomes. For the fiscal year 2023-24, Global Pharmaceuticals received only 3 market complaints, compared to 10 for Team Pharmaceuticals. This suggests that effective use of lean tools enhances efficiency and compliance. Global Pharmaceuticals' extensive use of lean tools across its supply chain improves performance, whereas Team Pharmaceuticals' limited use may lead to less effective problem-solving and quality control.

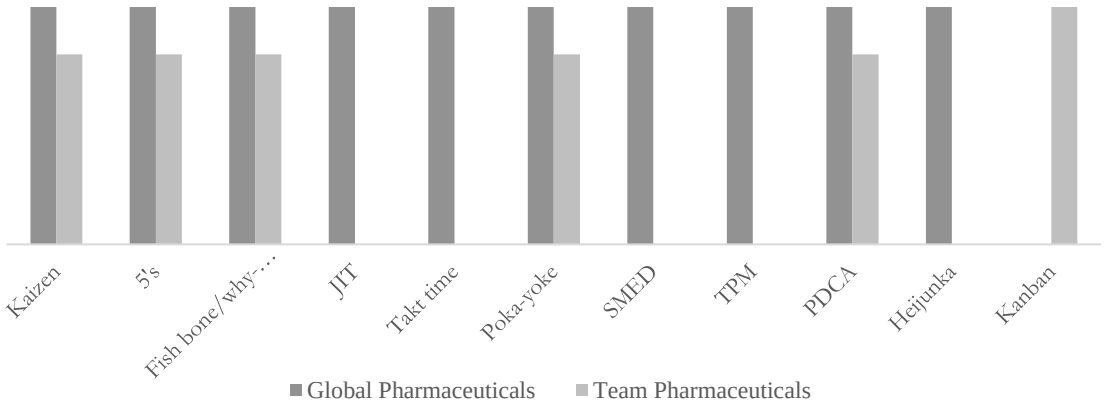

Fig. 13. Comparison of lean tools usage.

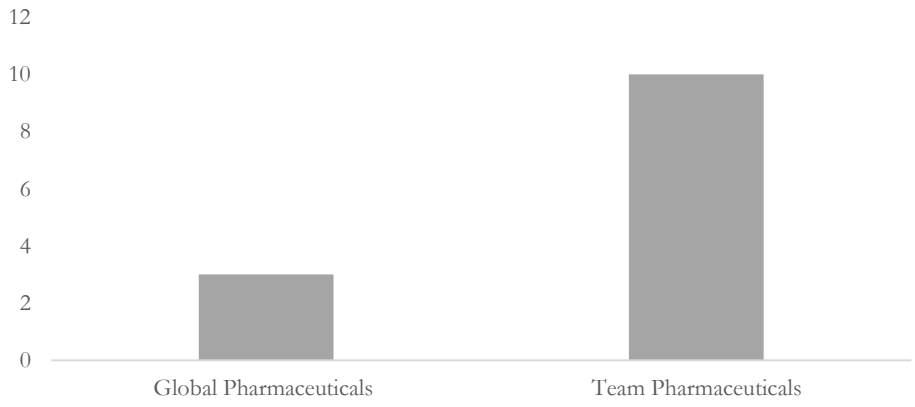

Fig. 14. Market complaint on 2023-24 fiscal years

7 | Recommendations

The data indicates that Global Pharmaceuticals benefits from using a broad range of lean tools, leading to fewer market complaints. To enhance performance, Team Pharmaceuticals should expand its lean toolkit to address additional areas of its processes. This could improve quality control and reduce complaints. Additionally, Team Pharmaceuticals could invest in developing its team's lean skills through targeted training programs and fostering a culture that supports continuous improvement. Exploring new methodologies and incorporating feedback loops into their processes can further drive efficiency and effectiveness.

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Author Contributions

The primary author, Abu Shahriar Partho, was responsible for leading the formulation of the concept, research design, data collection, formal analysis, and manuscript writing. Co-authors Md. Tanbin Haque, Fahmida Binta Fulzar Nabila, Bidhan Kar, and Md. Sohan Hossain played a critical role in project design, data assessment, and data verification. Additionally, they reviewed the supplemental cases and contributed substantively to the article's writing and refinement.

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Ethical Statement

This study does not involve any research with human or animal subjects conducted by any of the authors.

Data Availability Statement

Data is available upon reasonable request from the corresponding author.

Conflicts of Interest

The authors declare no conflicts of interest related to this work.

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