Applying Lean Manufacturing to Minimize Inspection Time in a Medical Device Company

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Abstract — *This research is conducted in medical devices manufacturing company that makes a product to be used on the treatment of female stress urinary incontinence resulting from urethral hyper mobility and intrinsic sphincter deficiency. The product consist of a family of products which and the device is commonly referred to as tension free, pub urethral sling. This research is the result of the initiatives of the Continues Improvement Department. It was identified waste time caused by off-line quality inspections in the product-assembly process and it is intended to reduce the waiting time in the manufacturing of the product. Lean Manufacturing tools were used in this project. The main objectives of this research were to reduce waiting time at least 20% and improve efficiency at least 10%. Some tools used to obtain the results were: balancing the production line, evaluating the line layout, implementing 5S to the sub assembly station.*

Key Terms — *Improvement, Lean Manufacturing, Inspections, Waste time.*

INTRODUCTION

The manufacturers are focus in produce with processes optimized to increase manufacturing productivity. For that reason, companies create departments dedicated to the process improvements. The Continuous Improvement department is composed of representatives of all areas.

In the Medical Devices Manufacturing company were initiated continues improvement initiatives. In the manufacturing of the product, were identified losses due to waste time caused by three (3) off-line quality inspections in the product-assembly process. For the quality inspections, the non-value added percentage was 90.2%, the line efficiency with twelve operators was 43.9% and the cycle time of 180.61 minutes/unit. This product was selected by the Continuous Improvement Department to implement improvements. The major cause for the waste time detected was related to the Quality Control inspections.

The objective of this research was to reduce the waste time due to Quality Control inspections during the sub-assembly process. The process requires three (3) inspections before the product is completed. With an efficient manufacturing process, the waste time will be reduced resulting in improving line efficiency and increasing the daily required output.

Research Description

This research was conducted in a Medical Devices company to reduce the waste time in the sub-assembly process for the urethral product. The Continues Improvement Department detected that the urethra product need improvements. The benefit of this research is increase productivity and decrease manufacturing costs.

Lean Manufacturing tools were used to study the existing product manufacturing process that was identified by the Continuous Improvement Department for waste time reduction. The main root cause for the waste time was due to inspections by Quality Control Department.

Lean Manufacturing was implemented by balancing the production line, evaluating the line layout, applying time reduction in the line, and implementing 5S mythology to the sub assembly stations. The expected results after the implementation of lean manufacturing tools were:

standardization of the work, continuous flow in the line and decreasing the work time per operation.

The research will demonstrate the benefit of implementing Lean Manufacturing tools to improve the manufacturing process. The line output will increase, the waste time will reduce the overall manufacturing cycle time will reduce.

Research Objectives

The objective of this research will be to assess how the waste time in the manufacturing of the urethral product can be reduced. The main objectives of this research is to reduce the waiting time of the sub assembly process at least 20% and improve the line efficiency at least 10% of the cycle time. In addition, obtain a continuous flow and decrease the time at least 10%. It is intended to implement 5S on the sub assembly stations. Determine the quantity of operators by operations and reduce resources utilization.

Research Contributions

The research will contribute to provide a more efficient in the manufacturing process of the product. During this research is used the Lean Manufacturing tools like 5S to all sub assembly stations, time standards to each sub assembly in the production line. In addition metric measures and flow diagrams were included as part of this research. The production line will improve and the waste time will be reduced after the implementation of the tools. This project will help in the optimization of the production line; as a result the company will be more profitable since the cost will be reduced and productivity will increase. This research is use to optimize the product manufacturing.

LITERATURE REVIEW

This literature section presents the information that will be discussed during this research. The terms defined are associated with Lean Manufacturing tools.

The information contained in this section provides key information of this research to the readers. This section covers the relevant literature and the research background. This research used the Lean Manufacturing tools to reduce waste time.

Medical Device Definition

The Federal Food Drug & Cosmetic (FD&C) Act establishes in section 201(h) that it will be regulated by the Food and Drug Administration (FDA) as a medical device if a product is labeled, promoted or used in a manner that meets the definition of a device and is subject to premarketing and post marketing regulatory controls. According to definition a device is: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes." [1]

Product Overview

The product of this research is used as indicated for the treatment of female stress urinary incontinence resulting from urethral hyper mobility and/or intrinsic sphincter deficiency. The system comprises ergonomic introducers and a polypropylene mesh sling implant encased in a protective sheath with green guide tubes at each end of the sheath. Connectors are attached to the distal ends of the guide tubes, and are designed to attach to the tip portion of the introducer needles. The device is terminally sterilized by ethylene oxide. When the product is finally in used the installation is as shown in Figure 1

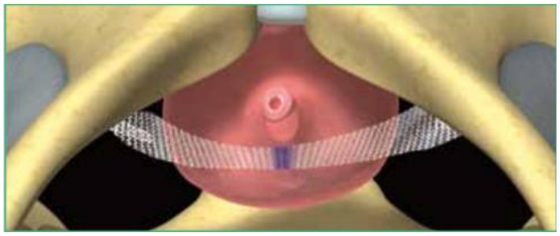

Figure 1
Product Installed

Lean Manufacturing Definitions

During this research the product manufacturing process was evaluated. The manufacturing process consists on the following steps: Forming, Cutting, Pin Insertion, Pre Swage, 1st Swage, 2nd Swage and Tap Sealing. Waste time was identified by the improvement team and it was determined to apply Lean Manufacturing tools to reduce the waste time and improve productivity.

The Lean Manufacturing term was originated during the post World War II era in Japan. The creator was Taiichi Ohio, who was a Toyota executive of the production area detect a problem of high variety production required to serve the domestic Japanese market. Lean Manufacturing is an operational strategy oriented toward achieving the shortest possible cycle time by eliminating waste. It is a key thrust is to increase the value-added work by eliminating waste and reducing incidental work. The technique often decreases the time between a customer order and shipment, and it is designed to radically improve profitability, customer satisfaction, throughput time, and employee morale. The concept of Lean manufacturing is an applied methodology of scientific, objective techniques that cause work tasks in a process to be performed with a minimum of non-value adding activities resulting in greatly reduced wait time, queue time, move time, administrative time, and other delays.

The benefits generally are lower costs, higher quality, and shorter lead times. The term lean manufacturing is coined to represent half the human effort in the company, half the manufacturing space, half the investment in tools, and half the engineering hours to develop a new product in half the time. Some of the characteristics of lean processes are: single-piece production, repetitive order characteristics, and Just-In-Time scheduling, short cycle times, continuous flow, compressed space, multi-skilled employees, flexible workforce, empowered employees and high first-pass yields with major reductions in defects.

Lean Manufacturing incorporates the use of Takt time, continuous flow manufacturing, cellular manufacturing, and pull production scheduling techniques such as Kanban. "In lean manufacturing seven types of waste were defined:

- Overproduction (production ahead of demand);
- Defects (any product/service that the customer is unwilling to accept);
- Transportation (moving products when it is not actually required to perform a processing step);
- Waiting (any resources/materials staying idle);
- Inventory (materials not being completely transformed);
- Motion (resources moving more than is required to transform the material);
- Processing (unnecessary or processing over the minimum necessary for material transformation)." [2]

Takt Time will be used to study the time in the production line. The Takt time is defined as "the desired time between units of production output, synchronized to customer demand" [3]. The concept carries backward through a process stream. The effects caused by the Takt time are:

- Production Stability-by limiting overproduction, it stabilizes the system and prevents buildups of inventory and the subsequent stops and starts.
- Work cell Design-Takt time helps cell designers. In an ideal work cell, all tasks are balanced, they all require the same time to execute and that time equals the Takt time. If any operation requires more than the Takt time, the cell cannot produce at the necessary rate.

The Takt time will be used to perform the appropriate manufacturing line balancing and establish a continuous flow to reduce the in process work. In addition, Takt time metrics will be implemented to measure the performance. Equation (1) is the formula used for the Takt time:

$$T = \frac{Ta}{Td} \quad (1)$$

Where, T= Takt time, e.g. [minutes of work / unit produced]; Ta = Net time available to work; e.g. [minutes of work / day]; Td = Time demand (customer demand), e.g. [units required / day]

Equation (2) gives the general number of operators to produce:

$$\text{Number of operators} = \frac{\text{OCT}}{\text{Takt Time}} \quad (2)$$

Where, OCT = Operator Cycle Time: Total time required for a worker to complete one cycle of an operation" [4].

Kaizen is a term that combines two words from the Japanese vocabulary—good and change. Commonly referred to "as change for the better," kaizen is a continuous improvement mindset that pursues elimination of waste. The Kaizen breakthrough methodology is a process where a cross-functional team is assembled for a one-week period to measure, analyze, improve, and sustain an improvement to a process. It is a very intense and focused process that relies on creativity rather than capital to make the improvements.

The 5S approach purpose is to organize the work area and place everything in a corresponding place as part of this research. This research proposes a waste relationship model that can be used for decision-making about trade-offs with the objective to reduce waste types (QC inspections) to the minimum possible level in a waste-dependent efficient system without jeopardizing its intended functionality. Moreover, this research identify, develops, and integrates a set of metrics; determines the waste relationship; and statistically verify the proposed waste relationship and the center point metric across different production planning scenarios and different manufacturing system complexities.

METHODOLOGY

Productivity, efficiency and cost reductions are the main goals in today's companies. The Lean Manufacturing tools are very effective to achieve these goals. According to the book "Today's Factory by Charles Standard and Dale Davis" [5], the strategy used in the companies to reduce process variability, reducing system cycle times, eliminating waste in the manufacturing process and supply chain, from receipt of order to delivery of product and payment. Applying the lean tools in the manufacturing area due the companies goals and profit has been focus on financial results reacting on the government strategies of reduce incentives.

Investigation Design

The methodology used in this research was based on lean principles and tools as a system. The lean principles and tools were evaluated to determine how to implement lean manufacturing in this study research. The lean manufacturing characteristics found were as follows:

- Minimum inventory in the form of raw material, Work in Process (WIP), finished goods;
- Minimum product non-conformances, rework, rejects, and returns;
- Minimum production losses through unplanned and planned downtime, changeover and transition time, rate reductions and short stops, and quality problems;
- Minimum system cycle times and minimum delay times between processes;
- Minimum variability in production rates and processes;
- Minimum unit cost of production;
- Excellent on-time delivery performance, customer satisfaction, and gross profits;
- Continuing focus and improvement.

An important key in lean manufacturing is to eliminate the waste in the process. The term waste is defined as anything that adds cost, but does not add value. In order to identify the waste, the process shall be known. A key tool for understanding the processes is to do value stream mapping for the product line. Then team must work to remove non-value adding activities, and add more value adding activities. The waste identified during this process is the Waste of Waiting, which disrupts flow. In lean manufacturing this is one of the more serious wastes. During this investigation the total waste time due to quality inspections will be reduced.

Lean Manufacturing Elements

The Five Primary Elements for lean manufacturing are: Manufacturing Flow, Organization, Process Control, Metrics, and Logistics. These elements represent the various facets required to support a solid lean manufacturing program.

- Manufacturing Flow: The aspect that addresses physical changes and design standards that are deployed as part of the cell;
- Organization: Focus on identify people's roles/functions, training in new ways of working, and communication;
- Process Control: The aspect directed at monitoring, controlling, stabilizing, and pursuing ways to improve the process;
- Metrics: The aspect addressing visible, results-based performance measures; targeted improvement; and team rewards/recognition;
- Logistics: The aspect that provides the definition for operating rules and mechanisms for planning and controlling the material flow;

Manufacturing Flow sets the foundation for change. People see activity on the manufacturing floor, furniture or equipment being moved, machines and areas being cleaned up. Furthermore, there are visible changes in infrastructure relative to organizational roles and responsibility, new ways of working, and training of personnel. The visible presence of measurements reflecting current status, work instructions being posted at work stations, and machine changeover times recorded and improved. These primary elements complement one to another and are all required to support each other as part of a successful implementation. These changes will help to the line improvement implementation for this investigation. The current layout will be evaluated to determine improvements and design a new layout.

Design a Team

A team will be develop, and deploy the lean manufacturing program. The team roles within the team will be assigned and training to the team will be provided to ensure that all members understand their roles and why were selected for the assignment.

The team will need to generate a project charter and project milestone plan. The project charter is a document that defines the project's purpose, objectives, and outcomes. The milestone plan identifies major segments of the project, the time frame for completion, and a sequence of major events. The milestone plan will be based on a lean manufacturing road map which provides a common understanding for the team as to specific phases of the project.

Kaizen

A kaizen strategy will be implemented as part of research efforts to obtained improvement in the production process. Implementing Kaizen will move the organization's focus towards continuous improvement. The end goal is to gain a competitive edge by reducing costs and improving the quality system.

Result Analysis Process

The purpose of the analysis results will be to determine if the implementation of lean manufacturing tools to reduce the waste time in the production line. The line efficiency will be improved by updating the current process layout. Manufacturing layout crucially affects the performance. Layout decisions once made and implemented are not easy to change. Machines will have been screwed to the floor and have service ducting for electric power, computer links, and the required utilities. It is important therefore to get the most efficient layout in the first place and to build-in some flexibility so that the layout can retain its efficiency with changing volumes and products. The layout flow patterns arrange the process steps in a natural flow order, link process steps to minimize cycle time and travel distance, eliminate crossover points, and simulate a continuous flow process by putting internal customers and suppliers next to each other. This research is intended to reduce the cycle time and flow distance.

The uniform time interval between workstations is called cycle time (which is also the time between successive units coming off the end of the line). At each workstation, work is performed on a product either by adding parts or by completing assembly operations. The work performed at each station is made up of many bits of work, termed tasks, elements, and work units. Such tasks are described by motion–time analysis. The total work to be performed at a workstation is equal to the sum of the tasks assigned to that workstation. The assembly-line balancing problem is one of assigning all tasks to a series of workstations so that each workstation has no more than can be done in the workstation cycle time, and so that the unassigned (that is, idle) time across all workstations is minimized. The problem is complicated by the relationships among tasks imposed by product design and process technologies. This is called the precedence relationship, which specifies the order in which tasks must be performed in the assembly process.

Implement 5s

The 5s will be implemented to all subassembly stations. The goal is to release time for housekeeping and to make housekeeping as easy as possible. The best way to do this is to search for everything that creates unnecessary effort. Sort out unnecessary objects; mark all known problems, find leakages, and remove hazards. Arranging and fixing everything starting from the easiest and most efficient access. It is the efficient placement and arrangement of equipment and materials. Cleanliness is crucial for the acceptance of 5S. A cleaning standard must be in place with the resources assigned. Implement audits to maintain the standards.

Implementing this methodology is expected to accomplish the research objective of reduce the waiting time of sub assembly process at least 20%, improve line efficiency and cycle time at least 10%. It is expected that with the new layout and 5S implementation the objectives can be meet.

RESULTS AND DISCUSSION

In this chapter the results of the lean implementation are presented, analyzed and discussed. In addition, the benefits obtained after the implementation of the after implemented lean philosophy in the manufacturing process.

Data Acquisition

The initial stage consists of collecting all information that would potentially be required to reduce the waiting time in the manufacturing process. The data was collected using excel spreadsheets to document the time. The data gathering serve to give the information to select the proper lean manufacturing tools.

Process Time Study

The time study was performed by dividing the manufacturing process in each individual sub-assembly operation station. The time for each operation element was recorded. The data obtained per operation cycle time was evaluated. Figure 3 and Figure 4 below summarize the results obtained. Refer to (3), (4) and (5) for some equations used:

$$\text{Normal Time} = \left(\frac{\text{Time Worked} \times \text{Performance Rating}}{\text{No.units Produced}}\right) \quad (3)$$

$$\text{Standard Time} = \frac{(\text{Normal time})}{(1+\text{Allowances})} \quad (4)$$

$$\text{Rating} = \frac{\text{Observed rating}}{\text{standard rating}} \quad (5)$$

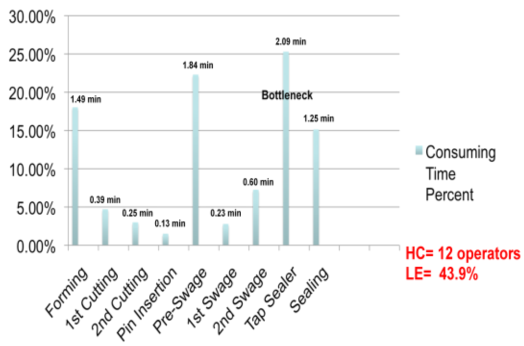

Figure 2
Line Efficiency

The Line Efficiency result for current manufacturing time based on the time study is 43.9% with a head count of 12 operators, as presented in Figure 3. The stages of manufacturing are being evaluated and a projected time was performed to balance the line and improve the line efficiency. The propose alternative to obtain a line improvement present an improvement of 33.75% (77.7% - 43.9%), as presented in Figure 4. The head count can also be reduced from 12 operators to 8 operators.

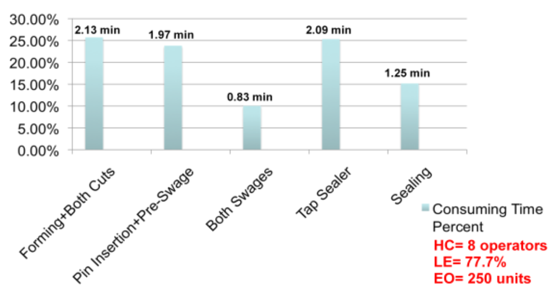

Figure 3
Proposed Line Balanced

Current Layout and Proposed Layout

As part of the manufacturing line study the current layout was evaluated to determine the non value added and value added time. The result demonstrates non value added of 90.2%, as indicated in Figure 4. It is recommended to change the line layout based on the proposed new sub assembly stages determined in the time study section discussed above. A proposed layout was design based on the time study results. The proposed layout demonstrates during simulation that the non value added result decrease to 51.7% and the value added increase to 48.3% which represent an improvement of 38.5%, as indicated in Figure 5. Table 1 summarizes the results obtained during the layout study.

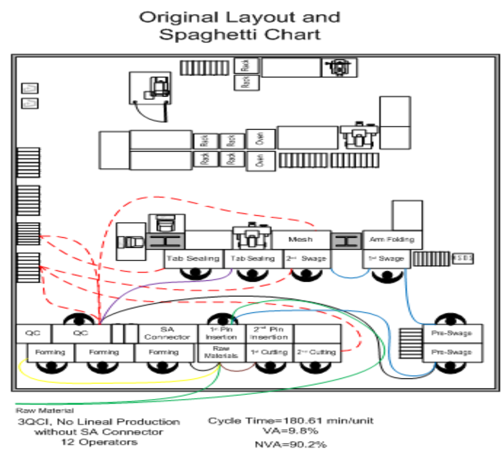

Figure 4
Original Layout

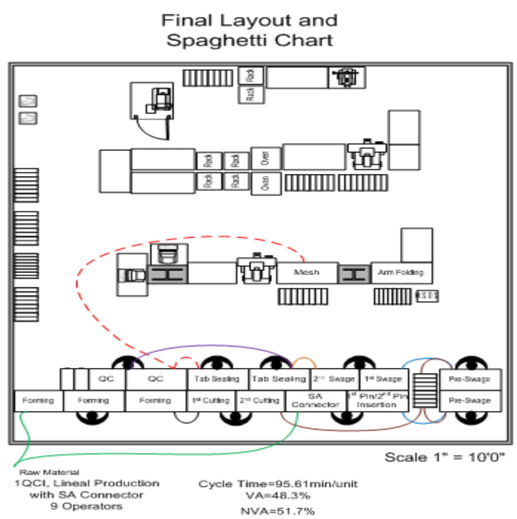

Figure 5
Proposed Layout

Table 1
Layout Reduction Distances

Layout	QCI	Cycle Time	Total Flow Distance	VA and NVA %
Initial Layout	3	180.61 min/unit	83.21 ft	9.8 , 90.2%
Proposed Layout	1	95.61 min/unit	13.1 ft	48.3 , 51.7%

Value Stream Mapping

In order to evaluate the waste time the improvement team performed a value stream mapping for the product line was conducted using the proposed layout. The Value Stream Maps documented the processes used to manufacture the product, both Value-Adding and Non-Value-Adding (Wastes) processes were identified. Data used was organized and analyzed then calculations were performed for cycle time, lead time, Takt time and value adding and non value adding activities.

Kaizen Implementation

Kaizen was used for the elimination of waste, reducing paperwork, improving productivity, production load leveling of amount and types, and standardized work. Kaizen was implemented as a daily activity with the purpose to do the work correctly. A kaizen Newspaper was generated with the actions and people to implement the actions identified. The progress of the project will be monitored through meetings and providing the information required in the Newspaper.

5S Methodology

The philosophy of the 5S has its roots in Japan, acronym of five Japanese words of the following meanings: Seiri (sort), Seiton (set in order), Seiso (shine), Seiketsu (standardize), Shitsuke (sustain). Implementing the 5S rules began by providing training to the manufacturing operators, so they can understand and implement the 5S's elements. The following was applied for 5S implementation:

- Sort: Sorting through all the tools, materials, etc in the work area and keeping only essential items. Eliminate all unnecessary items from the work area;
- Set in order: Order the workplace. Tools, equipment, and materials systematically arranged with a specific place and identified for the easiest and efficient access;
- Shine -keep the workplace clean as well as neat in a daily basis;
- Standardize- Maintain the control and consistency on all processes;
- Sustain - maintaining standards and keeping the facility in safe and efficient order;

To verify that each of the 5S is properly implemented a checklist was created to audit the working area during the manufacturing shifts. A 5S Audit form was created to audit the implementation of 5S in order to maintain the area complying with this methodology. Figure below represent the audit Form used for the manufacturing area.

CONCLUSIONS

The purpose of this research was to assess how to reduce the waste time in the manufacturing of urethral product. The Continues Improvement team was organized to evaluate, assigned the corresponding tasks and establishing due dates. As part of the evaluation it was determined to implement the Lean manufacturing methodology. Activities performed during the implementation of lean Manufacturing methodology were as follows: conducting a time study to balance the production line, performing layout evaluation, time reduction, and implementing 5S to the sub assembly stations. Lean manufacturing tools used during this study demonstrated satisfactorily results.

During the Process Time Study the time of each individual sub-assembly operation station was recorded. The line required production is 250 units/day equivalents. The initial standard time for each sub-assembly stations was calculated and the line efficiency (LE) obtained was 43.9%. The manufacturing line was balanced and the line efficiency was improved to 77.7%. This result demonstrate meet with the research objective to improve line efficiency at least 10%. With the line balanced the improvement obtained was 33.75%. The objective of reduce the resources utilization was met by the head count reduction from 12 operators to 8 operators.

The current layout was evaluated and a simulation was performed. As a result, the quality inspection non-value added activities were reduced from 90.2%.to 51.7%. The cycle time was reduced from 180.61 min/unit to 95.61 min/unit which represent a reduction in the cycle time of 85 min/unit. The results obtained demonstrated that the objective of design a new layout to obtain a continuous flow and decrease the cost of time at least 10% was achieved.

A value stream mapping was conducted with the proposed layout to document the process and identified the value adding and non value adding processes. The results obtained were: cycle time (7.36 min/unit), lead time (1245.5 min), Takt time (1.5 min/unit) and value adding (48.3%) and non value added (51.7%) activities. The result obtained for this simulation demonstrates improvement in the process.

As part of this study 5S and Kaizen was implemented in the sub-assembly stations. The application of 5S outcome was more productivity, standardization of work, continuous flow and more efficient process. The manufacturing personnel are involved in the process with clear expectations and clear instructions to perform the work.

The lean manufacturing tools implemented for the optimization of the product line demonstrate line improvement and waste time reduction. The objectives established in this study for the Medical Devices Company were accomplished. If the Medical Devices Company implements the application of the lean manufacturing tools used during this study the results will be reflected in cost reduction, reduction of waste time, more productivity and profit.

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