Implementation of Lean Six Sigma in a Manufacturing Cell of Orthopedic Devices to Reduce Waste

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Abstract *— Lean practices with Six Sigma methodology has been successfully applied in many industries to ensure the reduction of wastes and improve product quality. In this case study, the proposed implementation of lean six sigma for the industry of orthopedic devices is presented to reduce major types of waste. In the measure phase, data process was collected and a value stream map was developed to serve as a guide for lean activities. In the analysis of non-value added activities, a Pareto chart was used to focus project improvements in the major type of waste to reduce cycle time. A cause and effect diagram was developed to identify main causes of waste, while in the improve phase potential solutions were generated to reduce waiting time as the major source of waste. Finally to maintain the gains of the improvements, supporting methods are proposed in control phase.*

Key Terms *— Lean Manufacturing, Six Sigma, Value Stream Map, Waste Reduction.*

INTRODUCTION

Over the years, manufacturing companies have adopted tools to ensure the reduction of all types of waste to have a high operating efficiency systems in their facilities. One of the tools is lean manufacturing. Since its creation is considered a key to the success of any company doing business in a competitive environment. Lean principles have been successfully applied in many industries, including banking, hospitals, and government. Many manufacturing industries like medical devices industry, invest their efforts in continually improving of its processes to make better use of their resources and thus improve the economy of the organization. Lean manufacturing can help companies to reduce costs, improve lead time and most important eliminate wastes.

A design project will be leaded, having in mind the needs of continuous improvement in a company like orthopedic devices industry. It will allow improvements in the manufacturing process, identifying a problem by analyzing first the different sources of waste. Then proceed to the collection and analysis of data to complete a solutions proposal and implement them. The principles of Lean and Six Sigma methodology will be applied in order to remove as many defects as possible and thus achieve process optimization. To achieve process improvements it is necessary to:

- Identify sources of waste and reduce them, identifying the activities that do not add value to the process and modify them.
- Increase cycle efficiency process.
- Decrease Total Cycle Time.
- Develop a plan for implement improvements using Six Sigma Methodology.

After the completion of this project the percentage of waste in a manufacturing cell will be reduced. It will contribute to improve the production flow, save time, reduced lead time and increased the process cycle efficiency.

LITERATURE REVIEW

In the last years, many companies have given special attention to solving problems, currently, there are many process improvement tools and many of them are bring together in the philosophy of lean manufacturing.

Lean manufacturing is a philosophy focused in waste reduction in any process. The first person to integrate an entire production process was Henry Ford [1]. He lined up fabrication steps in process sequence, using special purpose machines to fabricate and assemble the components going into the vehicle within a few minutes and delivery them perfectly to the line side. However, Ford's system was unable to provide variety of models. Toyota take advantage to this situation and invented the Toyota Production System, improving Ford's idea to provide continuity in process flow and a wide variety in products offerings. The Toyota Production System was developed and refined between 1945 and 1970, is still growing today and used synonymously with lean manufacturing through the world. Toyota defines seven types of waste to target and eliminate [2]:

- Overproduction: this waste is producing more work or providing a service prior to it being required;
- Waiting: means idle time that cause's work flow to stop;
- Motion: any movement of people, material, that does not add value;
- Transport: it is the movement of any work or material that does not add value;
- Over processing: is putting more work or effort into the work required by the internal or external customer;
- Inventory: the excess stock of anything is waste;
- Correction of defects: it refers to all processing required in creating a defect and the additional work required to correct a defect;
- People's skill: known as the 8th waste, refers to the underutilization of people, not placing people where they can use their knowledge, skills and abilities to their fullest.

To identify and eliminate all types of waste, organizations could develop a value stream map (VSM) to allow everyone see the material and information flow of a product. A value stream is all the actions currently required to bring a product through the main flows essential to every product: the production flow from raw material into the arms of customer, and the design flow from concept to launch [3]. The value stream map is an essential tool because it forms the basis of an implementation plan, to subsequently utilize lean tools to eliminate waste. Once the companies identify the major sources of waste, tools such 5S, Just In Time, Kaizen, Kanban, Poka-Yoke, Yamazumi and others will guide companies through correction actions as to eliminate waste.

Just In Time is a principle to establish a system of manufacturing and supplying products at the right time, in the right amount, with neither defects nor waste [2]. Just In Time principle provides three basic elements to change a company's system: continuous flow, takt time and pull system [2]. Continuous flow allows material flow through operations without delay and enhancing defect detection. The takt time set the pace of the entire operation and the pull system allow material to flow without any inventory, reducing lead times and inventory carrying costs to supply the expected demand.

Kaizen is a series of practices were team charters are formed to brainstorm and discuss ways to eliminate waste in the work cell. Many of the lean manufacturing techniques are used to reduce or eliminate one or more wastes in the flow of production. A technique used to reduce waiting time is line balancing. This technique is used for leveling the work load across all processes in a cell or value stream, usually it is represented on a Yamazumi graph, which is a stacked column diagram representing the ways in which time is partitioned between production and problems.

Similarly there are other structured problem solving methodologies used in business. DMAIC is a methodology widely used for eliminating defects in any processes. The letters DMAIC are an acronym for the five phases of Six Sigma improvement: Define, Measure, Analyze, Improve, and Control. The origin of Six Sigma dates back from the 1980's, where Motorola believed quality measurement levels were not granular enough and the company developed the Six Sigma standard and methodology associated with it. The purpose of the first phase, Define is to have the team on the scope, goals and financial targets for the project. In Reference [4] some key steps in Define phase are established; the review of the project charter, validation of problem stament and goals, and the creation/validation of process map and scope.

The purpose of the Measure phase is to understand the key aspects of the current state of the process and collect relevant data. To collect reliable data team members must see what is going on in the process, it is recommendable to build up a value stream map.

In the Analyze phase the purpose is to pinpoint and verify the data to investigate cause and effect of relationships. Some key steps stated for the documentation of potential causes in the analysis phase are; the conduction of value analysis, calculation of Process Cycle Efficiency, analysis of the process flow, analysis of collected data and generation of theories to explain potential causes [4].

In the Improve phase the purpose is to optimize the current process, selecting the solutions and implementing them. Based on the documentation results, the Lean best practice is chosen to develop the improvements. Control is the last phase in this methodology, its purpose is to create standard operation procedures to document and sustain improvements, developing a plan to monitor results over time [4].

The Six Sigma and Lean Manufacturing are methodologies that have similar goals and results. When both are combined is referred to as Lean Six Sigma, a methodology which combined Lean methods and Six Sigma approaches. Lean Six Sigma's goal is growth, drives organizations not just to do things better but to do better things [5]. Lean Sigma appears to be the most promising technique to companies that have experiment with different strategies and techniques. The implementation of Lean Six Sigma show sustainable results in government agencies, health agencies and in the manufacturing industries among other, the implementation of this methodology has marked a change in the culture of these sectors. Reference [6] shows a research that supports how the implementation of Lean Six Sigma in a Medical Center assists the organization to carry projects to completion and to achieve rapid implementation of desired improvements.

In Reference [7] a study of compensation trends at manufacturing companies across the country is shown, it demonstrated that nearly 70 percent of the 1100 companies surveyed have implemented Lean practices in their operations, 58.6 percent of these companies are using Six Sigma. Companies need to master Lean Six Sigma to grow in today's competitive manufacturing environment [8].

Methodology

As discussed previously, the techniques of lean manufacturing have been widely used in the manufacturing industry to improve process. In this chapter some lean manufacturing techniques will be used together with the Six Sigma methodology.

Define

The Define phase, consists in understand the problem and identify it. The scope of the project is the reduction of over 15% of waste and reach daily requirement of pieces. The project charter in Figure 1, establish the problem statement, the project goal, the expected business and customer benefit, and set the stages for successful completion.

Project Name	***Implementing Lean Six Sigma to Waste Reduction in a Manufacturing Cell***		
Start Date	*02/15/2012*		
1. Process:	Develop a Value Stream Map to visualize entire flow production, recognize wastes and identify improvement opportunities. Identify the problem, conceptualization and design of the project, data collection and analysis, and propose solutions.		
2. Objectives and Project Description:	- Identify sources of waste and reduce them, identifying the activities that do not add value to our process and modify them. - Increase process cycle efficiency. - Decrease Total Cycle Time. - Develop a plan for implementing improvements using Six Sigma Methodology		
3. Business Results:	- Increased Production - Reduce cost. -Speed up delivery time/Reduce time to market		
4. Team members:	C. Vélez, J. Morales		
5. Project Scope:	15 % Waste Reduction in a manufacturing cell Reach Daily Requirements		
7. Benefit to External Customers:	An excellent product, that meets daily demand customer.		
8. Schedule:	D- Define M- Measurement		
	A- Analysis I- Improvement C- Control	Project Start	02/15/2012
		"D"Completion	04/01/2012
		"M" Completion	02/15/2012
		"A" Completion	04/01/2012
		"I" Completion	04/15/2012

Figure 1
Project Charter

In order to have a complete understanding of where the value is created, a SIPOC diagram is defined to identify all relevant elements of the process improvement project before it begins. This diagram identify; the suppliers of the Inputs that are required by the Process, the Inputs required for the Process to function properly, the Outputs of the process and the customers that will receive the Outputs. SIPOC diagram in Figure 2 shows the inputs and outputs with regard to a process flow in a manufacturing cell of orthopedics devices.

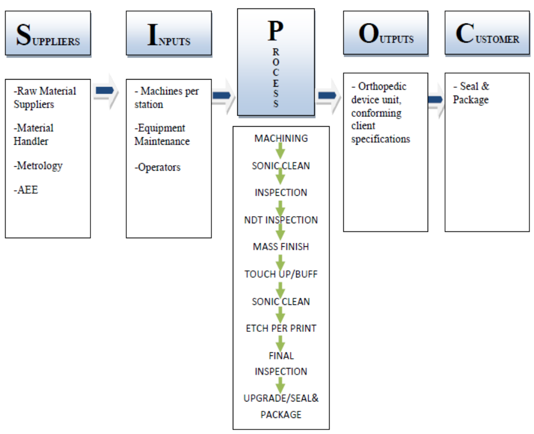

Figure 2
SIPOC Diagram

Measure

This phase focus on measurement system validation where reliable data on process speed is collected to expose the underlying causes of problems. To complete this phase a data collection plan is executed to establish baselines and validate a value stream map with data. In this phase ,work standards will be set by quantifying times and motions of the routine tasks performed by workers, which will give a basis to analyze tasks and determine which wasted motion can be eliminated. A worksheet for data collection was designed after walk the floor and enlist the different task for each operation. The data collection system in this project will be Lean Metrics, based on the seven types of waste. To collect the data of the process, it is necessary to identify a product family in the downstream process, usually the high runner product. The next step is the review of the basic production steps of each operation to outline them. When the elements of each operation are described step by step, it is possible to distinguish between activities that do not add value to the operation and classify them in a specific type of waste. Figure 3, shows an example of the data collection sheet created for NDT operation. Once data is collected, a value analysis is performed to classify each process step as value added, non- value added or incidental work (Business non-value-added).

Time Observation Worksheet					
OPERATION: **PENETRANT INSPECT**					
______ Other Details:		Family:			
Seq	Work Element	Observations:			2nd
		1	2	3	Lowest
		(min)	(min)	(min)	Time
	Check router, tag, lot	0.52	0.82	0.77	0.77
	Lad rack	0.12	0.20	0.18	0.18
	Water Washable Pen	0.28	0.27	0.14	0.27
	Drain	10.00	10.00	10.00	10.00
	Unload rack	1.52	7.60	58.47	7.60
	Clean	4.18	3.51	2.77	3.51
	Drier	10.00	10.00	10.00	10.00
	Dry (Over time)	12.99	27.26	46.63	27.26
	Dry powder	0.25	0.14	0.04	0.14
	UV light	10.00	10.00	10.00	10.00
	UV over time	1.71	25.30	46.81	25.30
	UV Inspection	0.56	0.71	0.87	0.71
	Unload Basket	0.65	0.37	0.31	0.37
	Move to next operatic	0.08	0.05	0.03	0.05
	Print Forms	1.24	1.93	1.30	1.30
	Documentation	1.18	0.99	1.05	1.05
	Fill N/A section	1.41	1.10	0.93	1.10
	Track in system	0.44	0.42	0.34	0.42
	Place in bin	0.03	0.06	0.04	0.04

Figure 3
Time Observation Worksheet

The second step of this phase is validate a value stream map with data, showing the main process steps relevant to the project scope, along with the work in process, lead times, customer demand and cycle times for each operation. Figure 4, shows operation and information flow in a Value Stream Map. The first operation in this manufacturing cell is machining, where different devices are created in five different machines, there is one operator per equipment to set machine and measure pieces. After each pieces are finished these lots feed the rest of the operations. The next station is Sonic Clean operation, where one operator prepares pieces to be cleaned and place them through six different tanks. The next operation is the dimensional inspection, where one operator measures and documents the dimensions of the pieces. Then the pieces are inspected by 0.50 operators in the non destructive test procedure, to detect material defects. After this operation, pieces

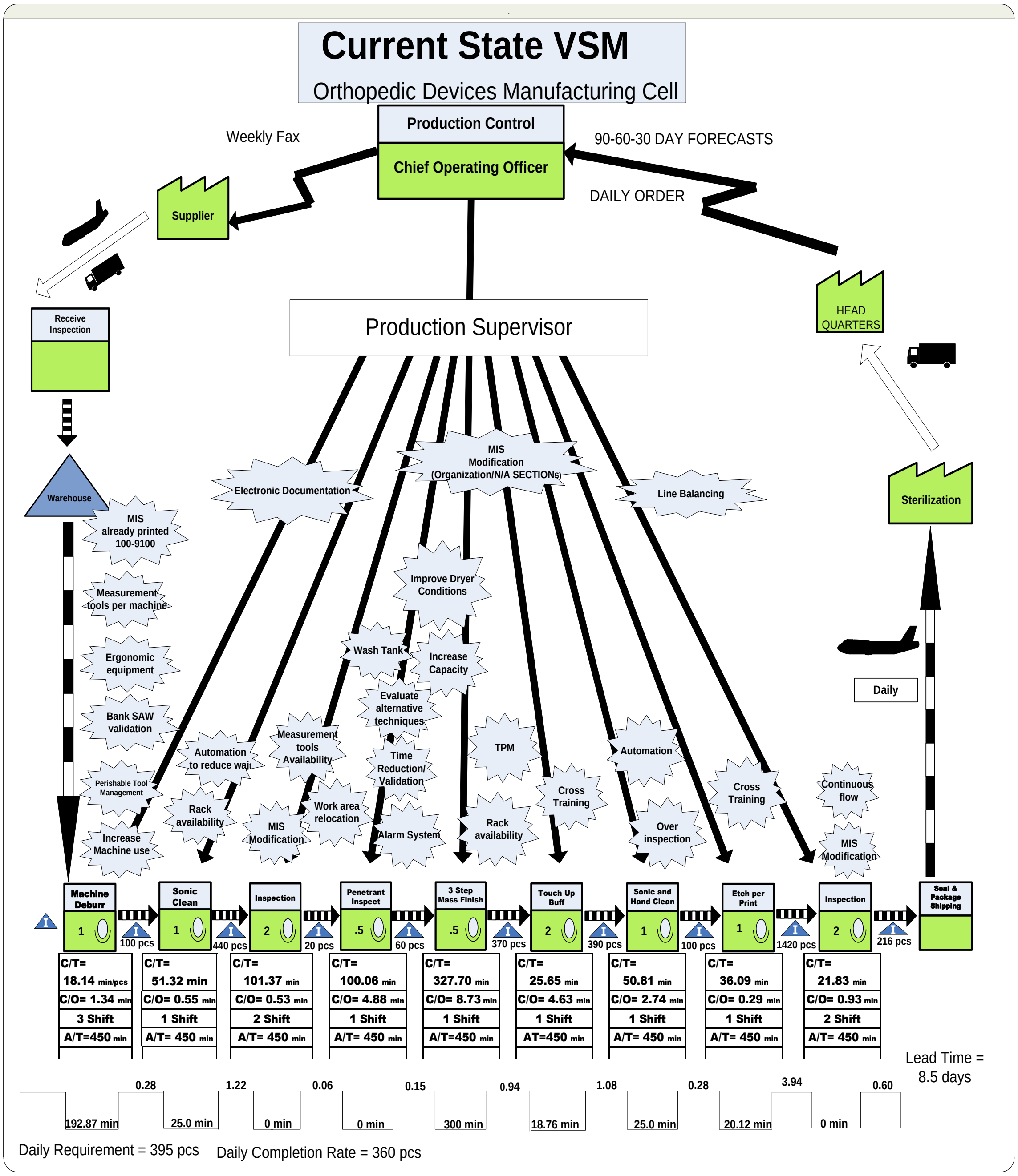

Figure 4
Current State Value Stream Map

are processed in three different tumblers, operated by 0.50 persons. The next operation is where the pieces are polished; there are two operators in this station. Then pieces return to Sonic Clean operation, where the same first operator prepare them for cleaning in tanks, and hand cleaning The last two operations are etching and inspection, each one have one operator. From the value stream map it can be distinguished bottlenecks areas where lots are waiting to be processed, inspection stations have the higher quantity of work in process.

The VSM shows some of the lean metrics used; Process Cycle Efficiency (PCE), takt time, takt rate and lead time. In Equation (1) the Process cycle efficiency indicates how efficient is a process in the transition of work in process to a finished product. The takt time in Equation (2) is the ratio of available time per daily requirement while the takt time in Equations (3) and (4), is the ratio of product demand per available time. Lead time in Equation (5) is the time taken from the order enters the process until it exits.

$$PCE = \frac{\text{Value - added time}}{\text{Process Cycle time}} = 59\% \tag{1}$$

$$\text{Takt time} = \frac{450\,\text{min}}{19.75\,\text{lots}} = 22.78\,\text{min/lot} \tag{2}$$

$$\text{Takt rate}_{\text{Req}} = \frac{395\text{units}}{750\text{min}} = 0.53\text{units/min} \tag{3}$$

$$\text{Takt rate}_{\text{Actual}} = \frac{360\text{ units}}{750\text{ min}} = 0.48\text{units/min} \tag{4}$$

$$\text{Lead Time} = \frac{\text{Work in Process (WIP)}}{\text{Average Completion Rate}} = \frac{2898}{360} = 8.05\text{days} \tag{5}$$

Figure 5 shows the waste walk data per operation. Tasks in each of the operations were classified in value added time or in different types of muda including incidental work (BNVA). The last two columns show the process cycle time and overall cycle efficiency.

Waste percentage analysis of the different types of wastes is represented in Figure 6. Value added activities represented the sixty four percent of the total time in the operation, followed by a fourteen percent of incidental work or inspection. The remaining waste categories range from 11% to 2% of total process time.

OPERATION	Processing VA	Over-Processing	Inspection	Motion	Transportation	Wait	CYCLE TIME
Machining	192.87	14.82	44.07	4.33	12.42	1.89	270.39
Sonic Clean	25.00	2.57	0.00	1.36	0.83	21.57	51.32
Inspection	0.00	13.55	83.81	2.69	1.32	0.00	101.37
NDT	0.00	6.06	1.48	1.76	0.60	90.16	100.06
Mass Finish	300.00	6.70	0.20	1.56	5.65	13.59	327.70
Touch Up/	18.76	2.11	0.70	0.58	1.51	1.98	25.65
Sonic Clean	25.00	5.92	9.52	0.36	5.73	3.44	49.98
Etch	20.12	5.71	6.50	2.17	1.60	0.00	36.09
F. Inspection	0.00	2.98	13.49	4.16	1.21	0.00	21.83
TOTAL	581.75	60.42	159.77	18.96	30.87	132.63	984.39

Figure 5
Waste Walk Summary Data

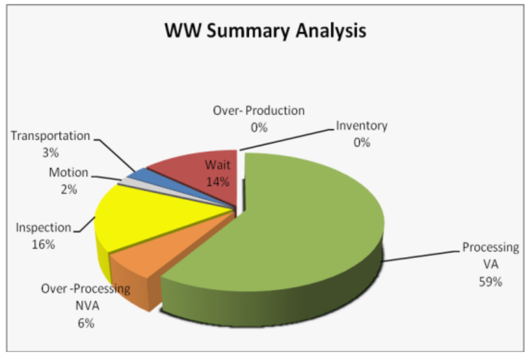

Figure 6
Waste Walk Percentage Summary Analysis

To visualize the type of waste that produces a significant overall effect in the process time the Pareto principle can be used as a model, to focus the improvement opportunities in the major type of waste found in the operation. In the pareto analysis the inspection time is not taken as a part of non value added activities, this activity is required by regulation and it is necessary to reach customer expectations, but add no real value from a customer standpoint. As the Pareto analysis shows in Figure 7, the first activity that should be attacked or minimized is the waiting time, followed by over-processing time.

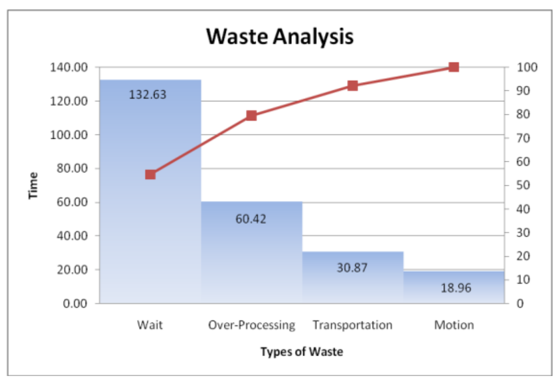

Figure 7
Pareto Waste Analysis

Analyze

Once the main sources of wastes are identified, different lean manufacturing tools will be analyzed for implementation. The objective of this phase is to use process data to identify the factors (X's) that affect the process output (Y's) significantly. Cause and Effect Diagram in Figure 8 identify the special roots of waste, to explore all the causes through operations in a manufacturing cell that induce wastes.

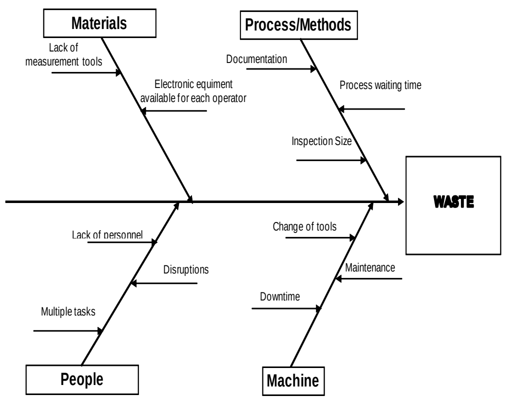

Figure 8
Cause and Effect Diagram

The Pareto chart highlighted the highest occurring type of waste, this implies that this phase will analyze improvement opportunities to reduce these type of wastes specifically. As can be distinguish from the waste walk summary data in Figure 5, the operations with major waiting time are NDT, Sonic Clean and Mass Finish.

In the operation of Sonic Clean waiting time represents the time in which the pieces are unattended once the process has finished in one tank, waiting to be placed in the next tank In the operation of NDT, waiting time is represented by the time spent waiting that the function of the penetrant liquid is completed, in addition there are some periods where the pieces are unattended, which represent waiting time. Once the major sources of waste are identified, it is important to analyze each operation to determine which tasks are essential although they contribute to waste, and identify those tasks considered as unnecessary or those that can be modified. Figure 9 and Figure 10 shows the waste walk data of the Sonic Clean Operation and NDT inspection respectively. As shown in waste walk diagrams, after the completion of some tasks, there are waiting periods because the operator is attending other process tasks. In order to reduce the overall waiting time of the process, improvements in this operations should be proposed. Moreover in these diagrams it is possible to observe some tasks or steps that could be eliminated; as print MIS and the documentation of non applicable sections in the MIS. The elimination or modification of these steps can reduce over-processing time and motion.

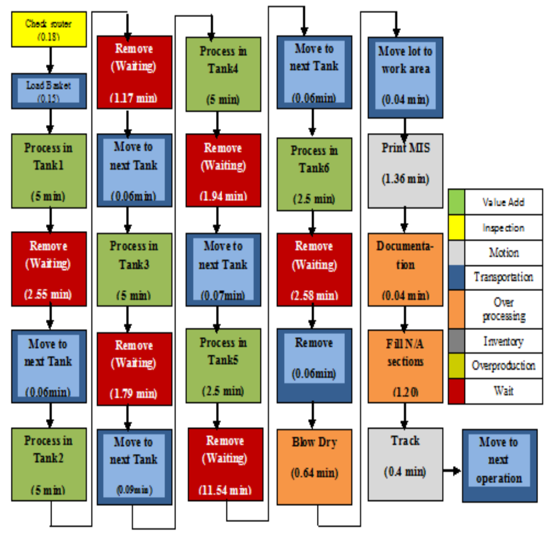

Figure 9
Sonic Clean Waste Walk Analysis

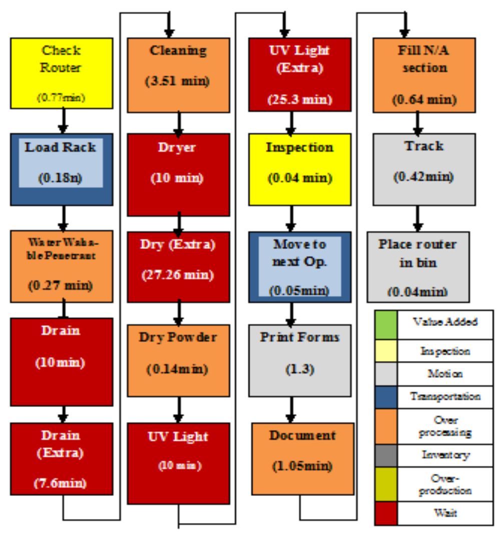

Figure 10
NDT Waste Walk Analysis

Improve

In this phase the objective is to change the inputs of the process(X's) to improve the outputs (Y's). In the analyze phase, cause and effect diagram was developed to explain the causes of the different types of wastes. Many of the causes described are the causative of waiting time and over-processing time, these causes are affecting the total cycle time. A wide range of potential solutions are identified in the VSM, and some metrics are evaluated to implement the short term solutions. The following practices could represent possible solutions to represent an specific type of waste:

- Line balancing
- MIS modification

Line balancing is the best way to distribute work elements across operators within a work area to meet daily requirements. To reduce waiting time in the Sonic Clean Operation and in the Non Destructive Test Station, another operator is required to meet the needs of both operations and reduce waiting time in these areas. When performing a line balancing for each station using Equation (6) to evaluate the needs of operators per station, its found that in the polishing station there are two operator but the determined ideal number of operators was one. Table 1 shows the results of line balancing in each operation.

$$\text{Ideal \# of Operators} = \frac{\text{Total Cycle Time}}{\text{Takt Time}} = \frac{25.65}{22.78} = 1.1 \qquad (6)$$

Table 1
Ideal Number of Operators

Operation	*C/T*	*Ideal*	*Actual*	*Diff.*
MACHINING	270.3	12	11	1
SONIC CLEAN	52.3	2	1	1
D. INSPEC	101.3	4	2	2
NDT	100.0	4	1	3
POLISH	25.6	1	2	-1
ETCH	33.0	1	1	0
FINAL INSP.	21.8	1	1	0

As Table 1 described the NDT operation needs theoretically four operators due to high cycle time, but this was far from reality, cycle time is high due to waiting time. It is possible the reduction of waiting time with the addition of one operator for Sonic Clean Station and NDT operation, this means 1.5 operator per station. With the performance of a line balancing it will be possible to have 3 operators in charge of the sonic clean station and the nondestructive inspection operation. With this modification an operator will be responsible for moving the basket from tank to tank in the two cycles of sonic clean and successfully reduce waiting time in the manufacturing process. The operator will also distribute his time in the operation of NDT in the same way, moving basket to the next tasks. Currently, NDT operator is also responsible for the operation of Mass Finish, by balancing the line and having another half-time operator, will allow in turn the reduction of waiting time in the Mass Finish operation. A 68 % of time reduction is expected with the implementation of this measure, it could be possible to reduce waiting time from 128.8 minutes to 41.5 minutes. In Figure 11, the expected reduction in waiting time is represented by a bar chart. From Table 1 it is possible to distinguish unbalanced operations, as dimensional inspection. In the VSM bottleneck can be identified in the inspection stations, it is important to balance these operations in order to have a balanced line where all the operations can meet daily requirements after improvements are implemented.

Also an MIS modification is proposed to reduce over-processing along operations. Indeed MIS is a regulated operation, its documentation is considered as over processing because have a poor design and contains sections that involve unnecessary extra effort. It is possible to made improvements in the MIS design, to standardize it, to the specific type of piece measured and reduce the unnecessary exertion used to fill not applicable areas in documentation. If this implementation is approved a 54% reduction of over-processing time is expected along operations.

Although waste by motion do not represent the major constraint in the process it can be reduced altogether with other implementations. With the elimination of the unnecessary MIS printing step in each station, it is possible to reduce this type of waste from 18.96 minutes to 11. 11 minutes. Previously printed documentation for each operation could be established as guideline to eliminate this motion.

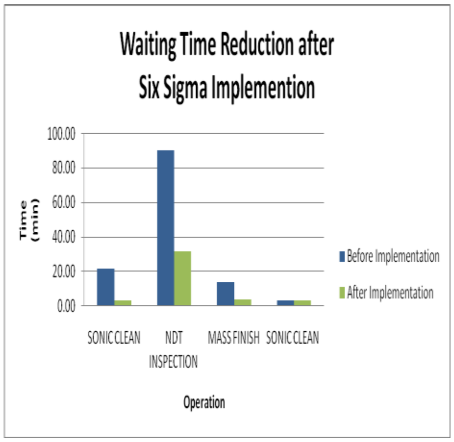

Figure 11
Expected Reduction in Waiting Time

In Figure 12, the possible overall cycle time reduction is illustrated. Total cycle time of the process can be reduced from 984.4 minutes to 862.4minutes, which represents a 12% of waste time reduction. while the overall process cycle efficiency could increase from 59% to 67%.

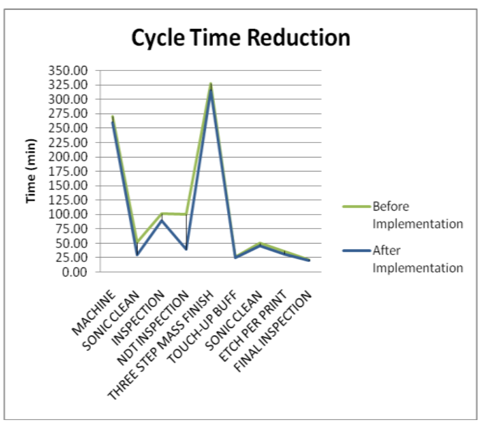

Figure 12
Expected Overall Cycle Time Reduction

Control

In the last phase of DMAIC, Control, the objective is to ensure that the processes continue to work well and produce desired output results. For maintaining the gains of the process, supporting methods and documentation are developed:

- Updated SOP's
- Cross- Training
- Future State Value Stream Map
- Yamazumi Chart

In Figure 13, tasks of NDT operation are shown, the expected time for each task after improvement is illustrated, in the left axis the accumulative operation time is showed. This chart is a visual aid, and help workers to immediately see where the delays are coming from. It can help the operator to visualize the tasks involved in the process and the time that each task should take to reach daily requirements.

To maintain the benefits of improvement some standard operational procedure changes are required, as well validations to ensure compliance to regulations. The proposed Six Sigma Value Stream Map suggests cross training as an improvement approach, multiskilled workers can handle any of the tasks in the work cell.

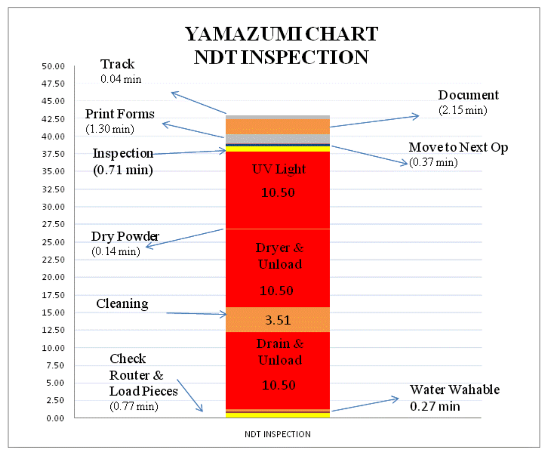

Figure 13
NDT Operation Yamazumi Chart

CONCLUSION

After the development of the five phases of DMAIC, it is possible to assert that sources of waste in a manufacturing cell of orthopedic devices were identified. With the aid of lean tools it was possible to developed practices that could improve the current process state. The proposed improvements in DMAIC cycle were in order to reduce waiting time, over processing time and motion with the purpose of reduce overall cycle time. In the first phase of DMAIC, Define, it was possible to establish project goals and expectations, specifying necessary resources to achieve business results. In the measure phase lean metrics were used. With the data collected from the process it was possible to identify waste and to calculate process cycle efficiency, lead time and takt rates. Actual takt rate is less than the required takt rate, which means that the process do not satisfy customer requirements because it does not meet daily demand of pieces. In the analyze phase the significant causes of waste were identified. A waste walk through operation was analyzed to determine how to improve the process eliminating steps or reducing tasks time in the operation. In the improve phase, potential solutions to reduce waste were prioritized and documented. Line balancing was proposed as a solution to reduce waiting time, while a MIS modification was also proposed to reduce over-processing time. The expected results of these improvements were estimated based in the tasks duration time collected. In the control phase, supporting methods are developed to produce output results. Yamazumi chart is a visual aid tool used in this phase to show expected times for each task.

The improvements proposals in this project were based on quantitative analysis. Each proposal was supported by a time study conducted in each of the tasks classified as waste or value added in each operation. With the implementation of proposed solutions it will be possible to efficiently group all resources, increasing efficiency and cost savings resulting from; the increased speed throughout the manufacturing and production cycle, and the reduction of waste time.

The enhanced data obtained from the Value Stream Map can provide feedback to guide continuous improvement and lead the company to a lean status. To reach this status there are some points of future research to mention.

- Research of measurement variation
- Validation of the NDT system process to reduce the time of the process.
- Focus in improvement measures to reduce other types of waste, as transportation and motion. The automation of cleaning areas can reduce motion, transportation and waiting time in this area.
- Identify quality issues, strive to resolve problems that add to re-work and increase the work in progress.
- Remove bottlenecks and delays to reduce work in progress.

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