Electrospinning Process Capacity Optimization In Medical Device Industries

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Abstract *— As part of the manufacturing cost reduction initiatives that support 2021 Operational Excellence Projects to promote continuous improvement on medical device industries; the Electrospinning (E-spin) process was found with capacity opportunities associated to inconsistency and high nozzle pass counts to construct a single corepin unit. With the intent to improve the E-spin corepin daily outputs by a 50%, the solution provided was to convert machine from single-needle to double-needle by maximizing machine free space and activating the secondary tecothate supply pump.*

E-spin capacity problematic was studied and analyzed through DMAIC methodologies based on Lean Six Sigma to identify all possible solutions. Hence, the E-spin process was not only improved by a 50% the corepin daily output; the machine time was reduced by a 30% finding consistency and reducing nozzle pass count. The implementations of these solutions reduced the E-spin weekend extended shift, providing a total of $124,530.11 in saving to the company.

Key Terms *— Corepins, DMAIC, Electrospinning, Multi-needle*

PROBLEM STATEMENT

On every organization that distribute goods and/or services, it is important to understand the key elements for operation, productivity, and supply chain management to capture business gaps. Medical devices industry is not the exception to this behavior. Along with providing high quality goods and/or services that fulfill customer's needs, the medical device industry understands that to establish a competitive and global market advantage; it is required to be creative on developing continuous improvement solutions to their production system without impacting goods and/or services quality. To achieve Operational Excellence, medical device industry promotes continuous improvement behaviors to target effectiveness and optimization by reducing overall production lead times and costs.

Research Description

On Quarter 4 of 2020, the Electrospinning (E-spin) Process that produce tecothane nanofibers deposition onto corepin and hypotubes pieces; was facing an increment on processing time. This problematic was associated to the inconsistency and high nozzle pass counts (around 28 – 32 passes) to construct a single corepin subassembly unit that meet tecothane outer diameter requirement for Boston Scientific heart failure leads. The e-spun coated corepin and hypotubes pieces are used create the internal cables and coil lumens during the molding process of the subassembly unit by allowing silicon integration onto e-spun fiber to prevent conductor abrasion of the silicone.

To meet daily manufacturing outputs and avoid impact on service level performance, it is required to work extended shifts (third shifts and weekends) on this station. Early Quarter 1 of 2021, an extended team was selected to attend this problematic in order to generate innovate ideas that solve the equipment efficiency problem in a cost-effective and timely manner. Therefore, an initial work has been performed in parallel with this project initiation.

Research Objectives

This research study intent to outline an 50% of improvement on E-spin corepin daily outputs by maximizing machine space to allocate corepin fixtures and activating the secondary tecothate supply pump to duplicate units produced per production cycle.

Research Contributions

The Electrospinning Process was part of 2020 Boston Scientific Dorado new product integration initiatives to reduce final lead manufacturing costs. This process was transferred with some process and capacity opportunities from the previous manufacturing site; therefore, this design project is intended to study, identify and provide solutions to support Boston Scientific 2021 Operational Excellence Projects for continuous improvement on manufacturing cost reduction initiatives.

This design project will be directly contributing improvements on manufacturing efficiency, labor capacity and overhead site metrics. Through Lean Six Sigma Methodologies, the E-spin process will be improved by achieving a higher production volume and minimizing production wastes. In addition, these techniques will optimize subassembly inventory management by improving the safety inventory stocks to minimize impacts to final assembly production.

LITERATURE REVIEW

To sustain competitiveness in global markets, regulated medical devices manufacturing industries are reinventing organization focus on developing strategies that promote continuous improvements practices based on Lean Manufacturing principles and Six Sigma methodologies to achieved Operational Excellence. These behaviors aim to improve operational system by targeting reduction on production cost while withstanding product and/or service value and quality to fulfill customer needs and expectations. To achieve overall operational cost reduction, a continuous evaluation on efficiency, labor capacity, overhead and poor quality is necessary to improve organization overall performance, effectiveness and competitiveness.

Organizations are continuously searching for productivity improvements opportunities since is a key success factor to stay competitive and securing the organization objectives [1]. To promote productivity effectiveness is necessary to evaluate product, equipment and systems performance; and understand efficacy to produce and/or transforms inputs on outputs. Focusing specifically on equipment efficiency; evaluation on machine availability, performance and quality is required to assess how capable the machine is to produce an output with the smallest amount of input resources [2].

Over the past two decades, organizations using common single needle electrospinning technologies has been facing challenges on low productivity rate of nanofibers due to electrospinning overall equipment efficiency [3]. Electrospinning is considered one of the most common technologies to produce nanofibers; and the basic machine setup for operation comprises a nozzle connected to a high-voltage DC power supply, a grounded collector and a solution reservoir to supply polymer solution [4]. Due to convenient and versatile applications of nanofibers on technologies such as: tissue engineering, wound-healing materials, energy, coatings, drug-released, sensors, filtration, and other applications; organizations have been facing capacity issues due to the nanofibers high-demand [5]. In the recent years, electrospinning technologies has been studied to modify and scale-up polymer injection systems. Alternative methods such as multi-needle and needleless technologies has emerged and found effective to improve productivity of nanofibers.

Multi-Needle electrospinning systems consist on introduction of multi-spinneret (multi-needle) components arranged on uniaxial configuration or in a circular geometry to allow multi-processing by increasing overall set-up throughput [6]. However, challenges on static and/or corona discharge on adjacent needles and polymer clogging difficulties on needle system still existed on Multi-needle systems. To address statics and alterations to electric fields, implementation of auxiliary electrode is necessary [7]. On the other hand, polymer clogging issues still a problem for this type of technologies and can be minimize by constant purging cycles and extensive needle system maintenance.

On medical device industry, converting a single needle electrospinning system to a needless electrospinning to increase overall equipment efficiency; requires a high capital investment due to the changes on injection system, implementation/revalidation work and overall device design testing. Needleless electrospinning systems are more suitable technologies to overcome up to millions production parts required to fulfill demand from biomedical and pharmaceutical industries [3]. Medical device industries such as Boston Scientific require a higher throughput volume that is achievable with the conversion to a multi-needle system. Hence, to overcome productivity issues related to electrospinning single needle system; current equipment efficiency opportunities can be evaluated through DMAIC methodologies based Lean Six Sigma practices to reduce equipment variations and eliminate process/equipment wastes.

DMAIC is the acronym that describes the roadmap used to improve performance based on five (5) phases of study: define, measure, analyze, improve and control [8]. Through the application of this improvement methodology on electrospinning single needle system, team members should: (1) Define equipment efficiency opportunities, (2) Measure actual efficiency, (3) Analyze opportunities and identify improvements, (4) Improve and implement ideas to increase equipment efficiency, and (5) Control and monitor implemented improvement. This methodology structure assures that all the possible opportunities to maximize machine efficiency and to reduce process/equipment waste are studied, evaluated and implemented; overcoming electrospinning process/equipment efficiency problems that is translated to increase organization profitability, effectiveness and competitiveness.

METHODOLOGY

To assess and study all possible outcomes to improve equipment capacity and inconsistency on higher pass counts on Electrospinning equipment, the project was started using DMAIC methodology based Lean Six Sigma practices. There is an initial work that has studied some alternatives to covert from a single needle to a multi-needle electrospinning system under Define, Measure and Analyze phases as follows:

- **Define Phase**
  - Meetings and interviews with Electrospinning Subject Matter Experts (SME's) to discuss capacity issues due to equipment capacity.
  - Problem statement and project chapter development
- **Measure Phase**
  - Process and equipment cycle time study.
  - Value Stream Map to study and measure effects on final subassembly manufacturing line.
  - Measure actual equipment efficiency variation due to nozzle inconsistency.
  - Measure overhead cost due to extended shift.
- **Analyze Phase**
  - Root cause analysis through Fish bone diagram
  - Identification and prioritization of potential elements that impact equipment efficiency.

The study performed through Define, Measure and Analyze phases will be documented as an initial work to this research project. However, this project methodology will be focusing on testing multi-needle conversion alternatives as studied on previous phases and providing results on equipment efficiency through DMAIC remaining phases (Improve and Control). The remaining DMAIC phases will cover the following:

- **Improve Phase**
  - Brainstorming sections to generate solutions ideas on multi-needle conversion to mitigate efficiency problems at lower cost as possible.
  - Define a validation strategy depending on solutions provided.

  - Define an implementation plan and possible impacts to manufacturing instructions.
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  - Define a validation strategy depending on solutions provided.
  - Define an implementation plan and possible impacts to manufacturing instructions.
- **Control Phase**
  - Training plan development for Electrospinning equipment operators.
  - Validate on multi-needle system conversion improvement against project goals.
  - Monitor and calculate months savings for one year against project goal saving as required per company policy.
  - Identify future improvement works as required.
  - Share project lessons learned.

Figure 1 shown Electrospinning Capacity Optimization Project Gantt Chart and the respective completions date per DMAIC phase to complete the project.

RESULTS AND DISCUSSION

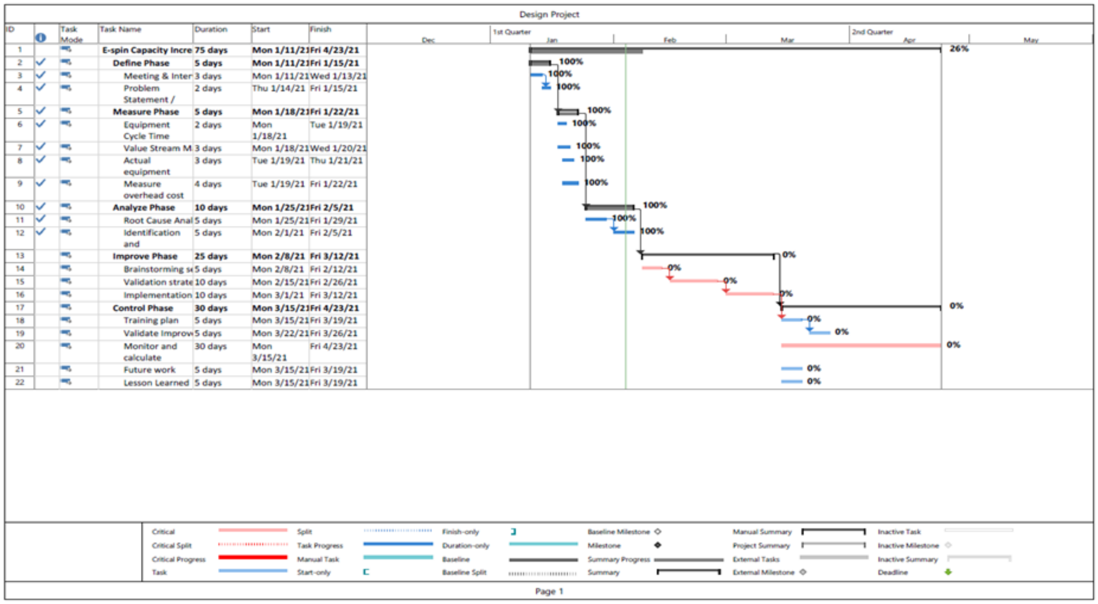
The Electrospinning capacity problematic was studied and analyzed through DMAIC methodology based on Lean Six Sigma practices. The results of each phase of this methodology are discussed as follows:

Define Phase

Due to the capacity issues confronted on Quarter 4 of 2020 on Electrospinning process, an extended team was created to understand and attend the problematic. Therefore, initial interviews with E-spin Subject Matter Experts (SME's) were conducted to generate and identified cost effective ideas to duplicate equipment output; without changing overall machine/device designs. As a result of these meetings, initial ideas on machine conversion from single to multi-needle system were identified as possible solution to solve E-spin capacity problem. Hence, a problem statement and project charter were developed to give formal structure to the project to attend the capacity problematic on the E-spin process.

Measure Phase

The Electrospinning process is divided in 5 main steps, independently the equipment is running hypotubes or corepins units (E-spin subassembly) as show in Figure 2. The main difference between hypotubes and corepins is the fixture used during the process and the equipment processing time. The first step is the E-spin solution preparation, that consist on dissolving a specific amount of tecothane pellets in a mixture of two chemicals; to then, use a mixer machine at predetermined revolutions per minute (rpm) and time to assure that all tecothane pellets are properly dissolved. This process normally takes about 3 hours to complete; however, the solution preparation process is not a constrain to the E-spin subassembly since a solution normally withstand for 3 production days and is performed during machine idle times. E-spin process set-up and machine processing is described from step 2 through step 6; and are the steps that where considered during the equipment and process cycle time calculation for the Measure phase. The E-spin process consists on loading corepin on fixtures to then load the assembly to the E-spin machine (step 3 and 4). Upon completion of E-spin equipment processing, the unloading process from machine and fixture are performed (steps 5 and 6). During machine processing (step 4) and operator waiting time for unit completion; the operator uses the idle time to load the next corepin on a secondary fixture to produce a complete cycle of processing (steps 4.1 – 6.1) and avoid any machine waiting time.



ID		Task Mode	Task Name	Duration	Start	Finish
1			**E-spin Capacity Incre**	**75 days**	**Mon 1/11/21**	**Fri 4/23/21**
2	✓		**Define Phase**	**5 days**	**Mon 1/11/21**	**Fri 1/15/21**
3	✓		Meeting & Inter	3 days	Mon 1/11/21	Wed 1/13/21
4	✓		Problem Statement /	2 days	Thu 1/14/21	Fri 1/15/21
5	✓		**Measure Phase**	**5 days**	**Mon 1/18/21**	**Fri 1/22/21**
6	✓		Equipment Cycle Time	2 days	Mon 1/18/21	Tue 1/19/21
7	✓		Value Stream M	3 days	Mon 1/18/21	Wed 1/20/21
8	✓		Actual equipment	3 days	Tue 1/19/21	Thu 1/21/21
9	✓		Measure overhead cost	4 days	Tue 1/19/21	Fri 1/22/21
10	✓		**Analyze Phase**	**10 days**	**Mon 1/25/21**	**Fri 2/5/21**
11	✓		Root Cause Anal	5 days	Mon 1/25/21	Fri 1/29/21
12	✓		Identification and	5 days	Mon 2/1/21	Fri 2/5/21
13			**Improve Phase**	**25 days**	**Mon 2/8/21**	**Fri 3/12/21**
14			Brainstorming se	5 days	Mon 2/8/21	Fri 2/12/21
15			Validation strate	10 days	Mon 2/15/21	Fri 2/26/21
16			Implementation	10 days	Mon 3/1/21	Fri 3/12/21
17			**Control Phase**	**30 days**	**Mon 3/15/21**	**Fri 4/23/21**
18			Training plan	5 days	Mon 3/15/21	Fri 3/19/21
19			Validate Improv	5 days	Mon 3/22/21	Fri 3/26/21
20			Monitor and calculate	30 days	Mon 3/15/21	Fri 4/23/21
21			Future work	5 days	Mon 3/15/21	Fri 3/19/21
22			Lesson Learned	5 days	Mon 3/15/21	Fri 3/19/21

Figure 1
Electrospinning Capacity Optimization Project Grantt Chart

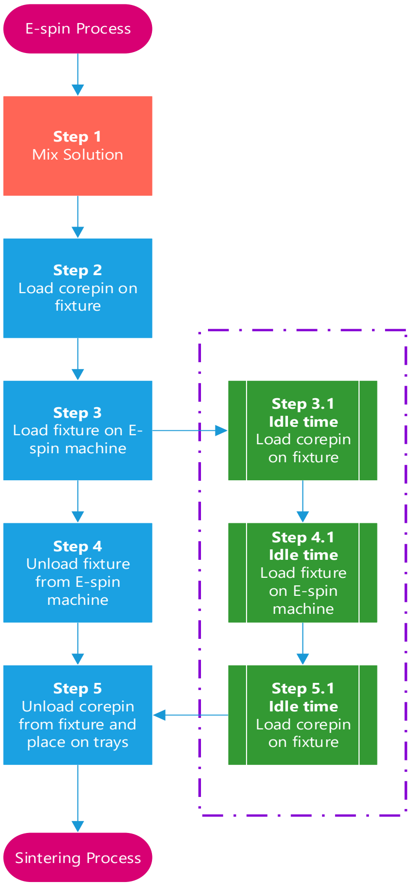
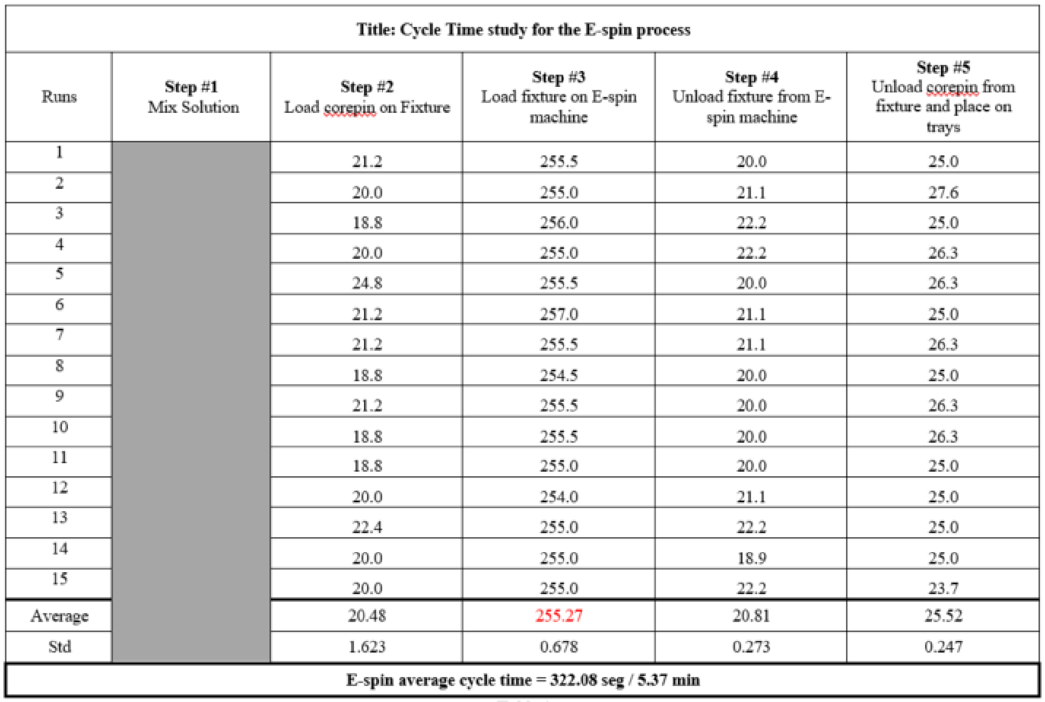


Figure 2
E-spin Process Flow Diagram

During the Measure phase, a complete analysis of equipment and process cycle time was performed to understand process deficiencies. The cycle time was measured to 15 runs using different operators from all shifts to have representative results. In addition, due to the variation on nozzle pass counts to complete a corepin unit between production days and shifts (around 28 – 32 passes), it was decided to use 30 pass counts during the development of this study. The results shown an average overall cycle time for the E-spin process of 322.08 seg (5.37 min); 255.27 seg (4.26 min) from the equipment time and 66.81 seg (1.11 min) from the process time as shown on Table 1. Moreover, the results revealed that step 3 has the longest period of the process time due to the E-spin equipment cycle time related to 30 pass count required to achieved tecothane outer diameter requirements. To understand in detail the material flow and process steps for the E-spin process, a Value Stream Map (VSM) was performed as shown in Figure 3. The VSM for E-spin process helped to describe every single task and identified potential wastes. During this analysis, the machine processing time (245.3s) still the biggest challenge for the E-spin process; however, due to the process nature and outer diameter design requirements there is not much available opportunities to reduce machine processing time without changing device design and/or process requirements. Nevertheless, machine processing time was not the only available waste identified for the E-spin process; machine available space in conjunction with operator idle time while running corepins set-ups where identified as additional process wastes as shown in Figure 4. These two opportunities in combination with nozzle pass count consistency are this project goal improvements to increase machine capacity and efficiency without impacting overall device design.



Title: Cycle Time study for the E-spin process

Runs	**Step #1** Mix Solution	**Step #2** Load corepin on Fixture	**Step #3** Load fixture on E-spin machine	**Step #4** Unload fixture from E-spin machine	**Step #5** Unload corepin from fixture and place on trays
1		21.2	255.5	20.0	25.0
2		20.0	255.0	21.1	27.6
3		18.8	256.0	22.2	25.0
4		20.0	255.0	22.2	26.3
5		24.8	255.5	20.0	26.3
6		21.2	257.0	21.1	25.0
7		21.2	255.5	21.1	26.3
8		18.8	254.5	20.0	25.0
9		21.2	255.5	20.0	26.3
10		18.8	255.5	20.0	26.3
11		18.8	255.0	20.0	25.0
12		20.0	254.0	21.1	25.0
13		22.4	255.0	22.2	25.0
14		20.0	255.0	18.9	25.0
15		20.0	255.0	22.2	23.7
Average		20.48	255.27	20.81	25.52
Std		1.623	0.678	0.273	0.247
E-spin average cycle time = 322.08 seg / 5.37 min					

Table 1

E-spin cycle Time Study

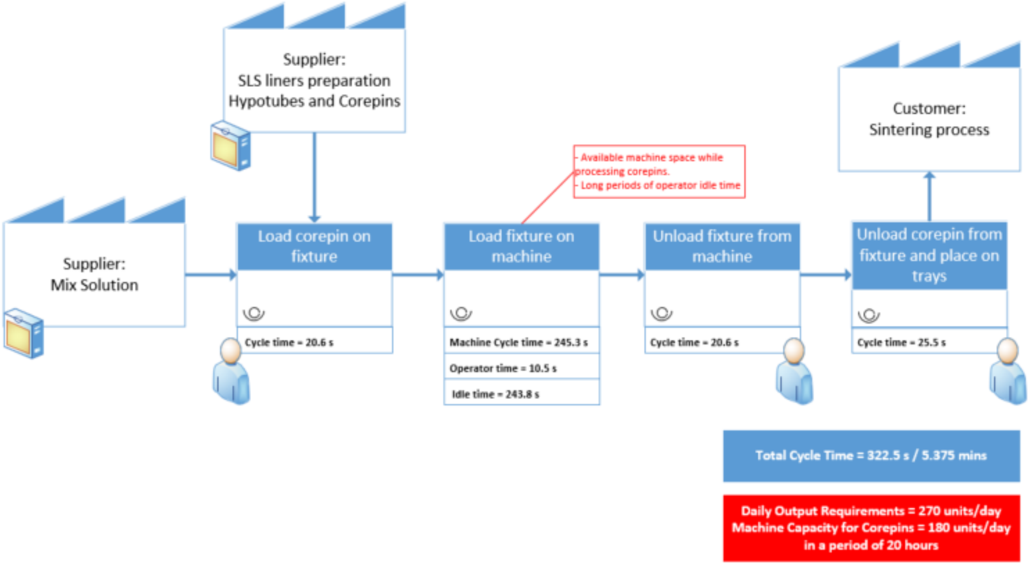


Figure 3

E-spin Process Value Stream Map (VMS) for Corepins

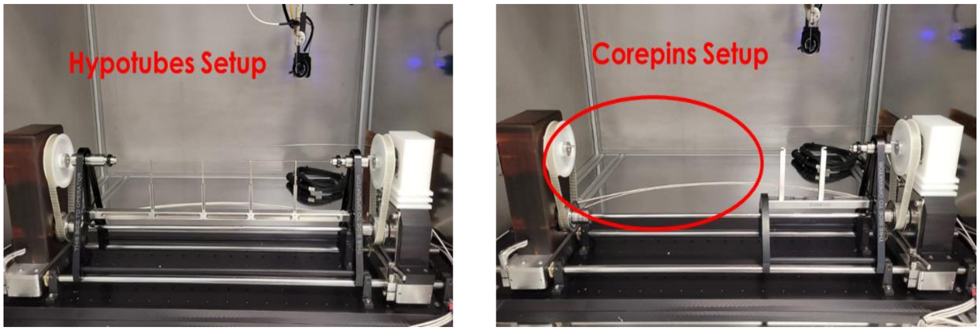


Figure 4

Hypotubes Machine Setup vs. Corepins Machine Setup

Due to the E-spin cycle time issues to complete a single corepin unit, the daily requirements of 270 units/day (number used to accumulate inventory at next subassembly station ~ 3 days of inventory) is impossible to meet since machine capacity only holds for an average of 180 units/day (in a period of 16 hours per day) without taking in consideration yield fallouts during processing. The remaining E-spin available time is used to construct hypotubes units, which runs at pass counts much lower (8 – 12 pass counts) than corepin units; even though, this set-up currently has a higher yield fallout in comparison to corepins. Therefore, to complete the production output gaps and avoid lack of inventory at the next subassembly line, it is necessary to coordinate extended production shifts during the weekends and work "hot sits" during operators breaks to maximize machine capacity. Hence, as part of the Measure phase the overhead costs related to the extended shifts where calculated and the results where the following:

$$Overhead\ cost = numbers\ operators\ (\ employee\ cost\ per\ hour)\ (working\ hours)$$

$$Overhead\ cost = (2\ regular\ operators)\left(\frac{\$16.99}{hour}\right)(48\ hrs)(1.5)$$

$$+\ (1\ temporary\ employee)\left(\frac{\$11.78}{hour}\right)(48\ hrs)(1.5)$$

$$\boldsymbol{Overhead\ cost = \$\,3,294.72\ per\ week}$$

As shown on above calculation, the company loss around $3,294.72 dollars per week as consequence of extended shift to achieve the production weekly requirement for the E-spin process. Since the beginning of E-spin capacity issue (week of October 11, 2020) and up to this calculation analysis (14 weeks), the company has a total loss of $46,126.08. Therefore, if the company continue with this capacity issues the estimated loss by the end of the year will become on $200,977.92 dollars (11 weeks from 2020 and 50 weeks from 2021).

Analyze Phase

In addition to machine space and operator idle time opportunities found during the VSM development; to assure all the potential root causes for E-spin capacity issues where addressed and analyzed, a cause and effect analysis was performed using a Fish-bone diagram as shown on Figure 5. The blocks red-dashed marked where selected as potential root causes with impact E-spin machine capacity due to high pass counts to complete a single corepin unit.

To analyze and provide a source of evidence that potential root cause theories has an impact on equipment capacity, specific testing where completed and results shown that 6 out of 8 theories where found with potential impact on E-spin machine capacity and to be addressed on the execution of this project.

Improve Phase

After confirming potential root causes for E-spin capacity issue, each component was evaluated for solutions through brainstorming sections during the Improve phase. These sections intention was to generate cost effective ideas to solve the E-spin capacity problem and stop the capital loss related to extended shift during weekends. Table 2 explain in details the proposed improvement solutions to solve the E-spin capacity issue and shown that 4 out of 6 potential causes were solved by implementing quick solutions. These were "quick wins" solutions found during the Fish-bone diagram execution that helped the E-spin process to gain some stability and reduction on pass counts while running corepin units. With these solutions, the E-spin process reduced the pass counts from an average of 28 – 32 passes to 18 – 22 passes; reducing machine processing time by a 30%. On the other hand, the remaining 2 potential causes where aimed to duplicate E-spin machine output by implementing a secondary nozzle system; which was the initial scope of this design project. The double nozzle fixture design/development was performed as creative and cost effective (equipment and fixturing total cost $3,963.97) solution to avoid critical machine design changes that could drastically increase project cost due to an implementation of a secondary head/motor to hold a second nozzle system. In addition, design changes to E-spin equipment was not an effective solution for senior management due to the complexity involved on design changes implementation and the impact on service level metrics of this product.

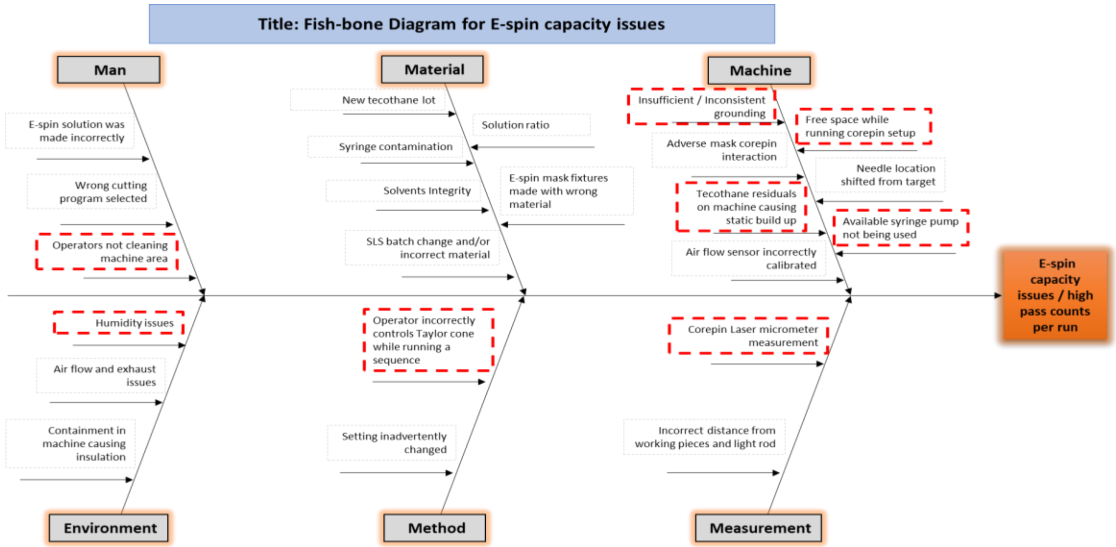
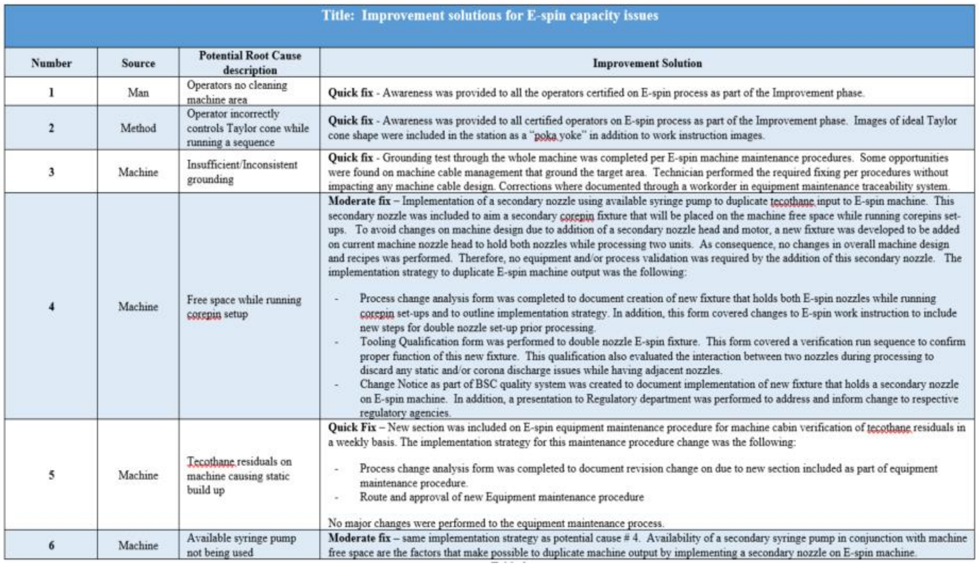


Figure 5

Fish-Bone Diagram for E-spin Capacity Issues



Title: Improvement solutions for E-spin capacity issues

Number	Source	Potential Root Cause description	Improvement Solution
1	Man	Operators no cleaning machine area	**Quick fix** - Awareness was provided to all the operators certified on E-spin process as part of the Improvement phase.
2	Method	Operator incorrectly controls Taylor cone while running a sequence	**Quick fix** - Awareness was provided to all certified operators on E-spin process as part of the Improvement phase. Images of ideal Taylor cone shape were included in the station as a "poka yoke" in addition to work instruction images.
3	Machine	Insufficient/Inconsistent grounding	**Quick fix** - Grounding test through the whole machine was completed per E-spin machine maintenance procedures. Some opportunities were found on machine cable management that ground the target area. Technician performed the required fixing per procedures without impacting any machine cable design. Corrections where documented through a workorder in equipment maintenance traceability system.
4	Machine	Free space while running corepin setup	**Moderate fix** – Implementation of a secondary nozzle using available syringe pump to duplicate tecothane input to E-spin machine. This secondary nozzle was included to aim a secondary corepin fixture that will be placed on the machine free space while running corepins set-ups. To avoid changes on machine design due to addition of a secondary nozzle head and motor, a new fixture was developed to be added on current machine nozzle head to hold both nozzles while processing two units. As consequence, no changes in overall machine design and recipes was performed. Therefore, no equipment and/or process validation was required by the addition of this secondary nozzle. The implementation strategy to duplicate E-spin machine output was the following: - Process change analysis form was completed to document creation of new fixture that holds both E-spin nozzles while running corepin set-ups and to outline implementation strategy. In addition, this form covered changes to E-spin work instruction to include new steps for double nozzle set-up prior processing. - Tooling Qualification form was performed to double nozzle E-spin fixture. This form covered a verification run sequence to confirm proper function of this new fixture. This qualification also evaluated the interaction between two nozzles during processing to discard any static and/or corona discharge issues while having adjacent nozzles. - Change Notice as part of BSC quality system was created to document implementation of new fixture that holds a secondary nozzle on E-spin machine. In addition, a presentation to Regulatory department was performed to address and inform change to respective regulatory agencies.
5	Machine	Tecothane residuals on machine causing static build up	**Quick Fix** – New section was included on E-spin equipment maintenance procedure for machine cabin verification of tecothane residuals in a weekly basis. The implementation strategy for this maintenance procedure change was the following: - Process change analysis form was completed to document revision change on due to new section included as part of equipment maintenance procedure. - Route and approval of new Equipment maintenance procedure No major changes were performed to the equipment maintenance process.
6	Machine	Available syringe pump not being used	**Moderate fix** – same implementation strategy as potential cause # 4. Availability of a secondary syringe pump in conjunction with machine free space are the factors that make possible to duplicate machine output by implementing a secondary nozzle on E-spin machine.

Table 2

Improvement Solutions for E-spin Capacity Issues

Control Phase

After completing the tool qualification form and presenting to regulatory department the change notice that implement the secondary nozzle to the E-spin machine, all the E-spin product builders were trained on the new instructions included as part of the manufacturing instructions. In addition, a complete demonstration using double nozzle set-up was provided to answer and clarify all product builder questions/doubts during the processing.

To assess and validate this design project improvement against project goals, a new Cycle time study and Value Stream Map were performed reflecting improvements after the double nozzle implementation. The results shown an average reduction on step 3 of 79.97 seg (1.33 min) after the improvement's implementation.

After the improvement, the E-spin machine was found to be capable to produce the daily output requirements of 270 units/day in 9 hours of production. Before the improvement, the machine only holds for 180 units/day in a period of 16 hours per day. The rest of the machine availability was used to produce hypotubes units (approximately 5 productions hours). With this improvement, corepins daily requirement can be fulfill in 2 productions shifts. However, as per business decisions; the station was left to continue production for 3 shifts due to the yield challenges that hypotubes set-up currently present. In addition, manufacturing and engineering departments will have more flexible time for frequents preventive maintenance schedules and the capacity to increase inventories on the following subassembly manufacturing line avoiding any line stop due to a lack of inventory. Nevertheless, this project was able to reduce the extended shifts during the weekend after the implementation week of March 15, 2021; reporting a total save of $124,530.11 to the company (for remaining 39 work weeks of 2021) after subtracting all capital investment to implement the secondary nozzle.

CONCLUSIONS

The Electrospinning Process identified with processing time and capacity opportunities during Quarter 4 of 2020; has been successfully improved to maximized machine space by duplication production output with the implementation of a secondary tecothane supply nozzle. Through DMAIC methodologies based on Lean Six Sigma practices, the E-spin process was not only improved by a 50% the production output; the process was deeply studied and evaluated for all possible solutions to maintain a consistency on higher pass count that impacted equipment processing time. With operator's awareness and machine preventive maintenance implementations (quick solutions), the team was able to reduce E-spin machine time by a 30% with consistency on pass count between 18 to 22 passes; an additional contribution found during this project development. In addition, the innovative double nozzle fixture solution provided by the team to solve the capacity issues in conjunction with the 30% reduction in processing time, the E-spin process was able to reduce the extended shift on the weekend providing a total of $124,530.11 in saving to the company on 2021.

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