Electrospinning Process Capacity Optimization In Medical Device Industries

Author: Freddie Joel Rivera González

Advisor: Rafael Nieves, Pharm.D

Industrial Engineering and Systems

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

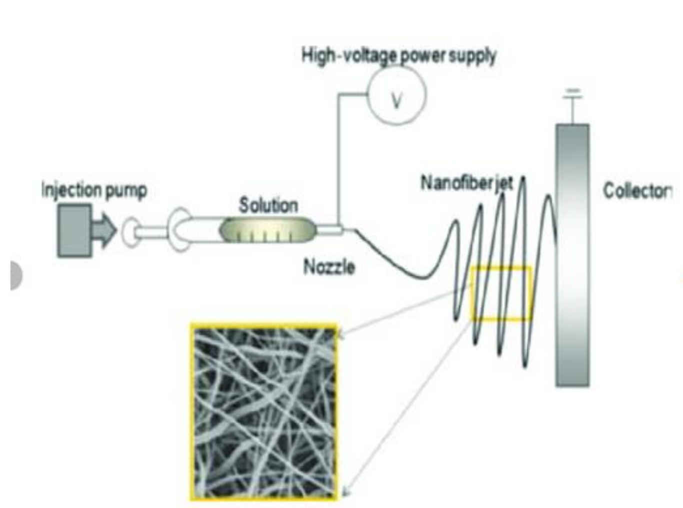
Introduction

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.

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.

Background

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 [1].



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 [2].

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.

Problem

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.

Methodology

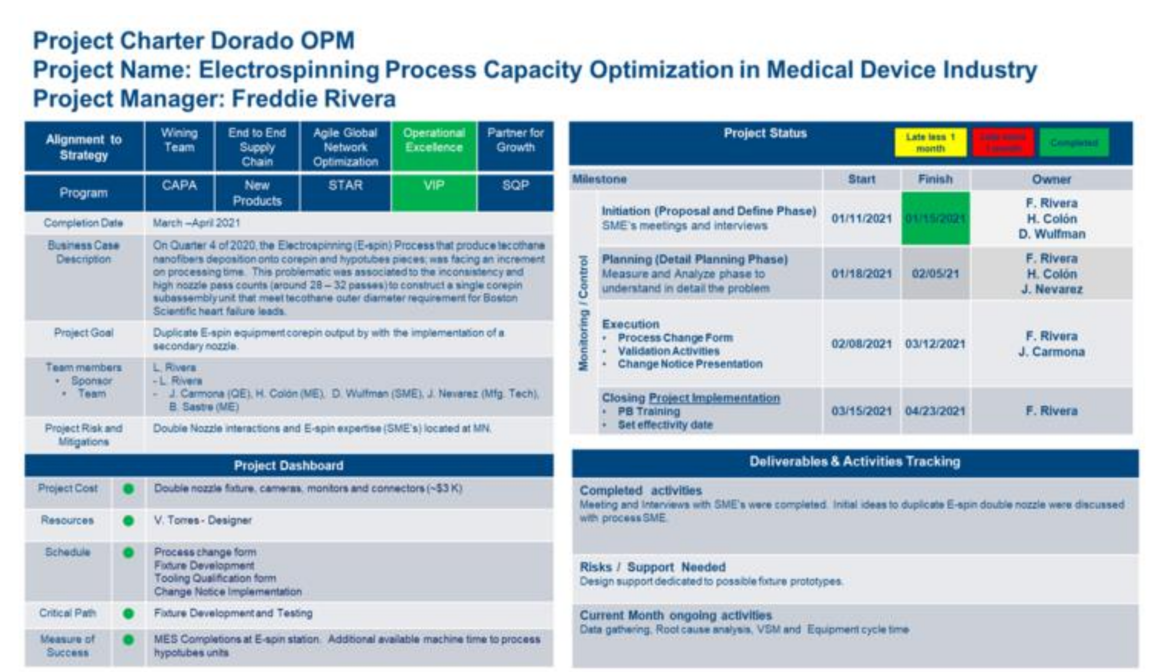
To assess and study all possible outcomes to improve equipment capacity and inconsistency on higher pass counts on Electrospinning equipment, the project was started using DMAIC (Define, Measure, Analyze, Improve and Control) methodology based Lean Six Sigma practices.

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:

- Extended team was created and interviews with E-spin Subject Matter Experts (SME's)
- Problem statement and project charter development.



Project Charter Dorado OPM
Project Name: Electrospinning Process Capacity Optimization in Medical Device Industry
Project Manager: Freddie Rivera

Alignment to Strategy	Wining Team	End to End Supply Chain	Agile Global Network Optimization	Operational Excellence	Partner for Growth
Program	CAPA	New Products	STAR	VIP	SQP

Completion Date	March –April 2021
Business Case 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.
Project Goal	Duplicate E-spin equipment corepin output by with the implementation of a secondary nozzle.
Team members • Sponsor • Team	L. Rivera - L. Rivera - J. Carmona (QE), H. Colón (ME), D. Wulfman (SME), J. Nevarez (Mfg. Tech), B. Sastre (ME)
Project Risk and Mitigations	Double Nozzle interactions and E-spin expertise (SME's) located at MN.

Project Dashboard		
Project Cost	●	Double nozzle fixture, cameras, monitors and connectors (~$3 K)
Resources	●	V. Torres - Designer
Schedule	●	Process change form Fixture Development Tooling Qualification form Change Notice Implementation
Critical Path	●	Fixture Development and Testing
Measure of Success	●	MES Completions at E-spin station. Additional available machine time to process hypotubes units

Project Status (Late less 1 month / Late more 1 month / Completed)

Milestone	Start	Finish	Owner
Initiation (Proposal and Define Phase) SME's meetings and interviews	01/11/2021	01/15/2021	F. Rivera H. Colón D. Wulfman
Planning (Detail Planning Phase) Measure and Analyze phase to understand in detail the problem	01/18/2021	02/05/21	F. Rivera H. Colón J. Nevarez
Execution • Process Change Form • Validation Activities • Change Notice Presentation	02/08/2021	03/12/2021	F. Rivera J. Carmona
Closing Project Implementation • PB Training • Set effectivity date	03/15/2021	04/23/2021	F. Rivera

Deliverables & Activities Tracking

Completed activities
Meeting and Interviews with SME's were completed. Initial ideas to duplicate E-spin double nozzle were discussed with process SME.

Risks / Support Needed
Design support dedicated to possible fixture prototypes.

Current Month ongoing activities
Data gathering, Root cause analysis, VSM and Equipment cycle time

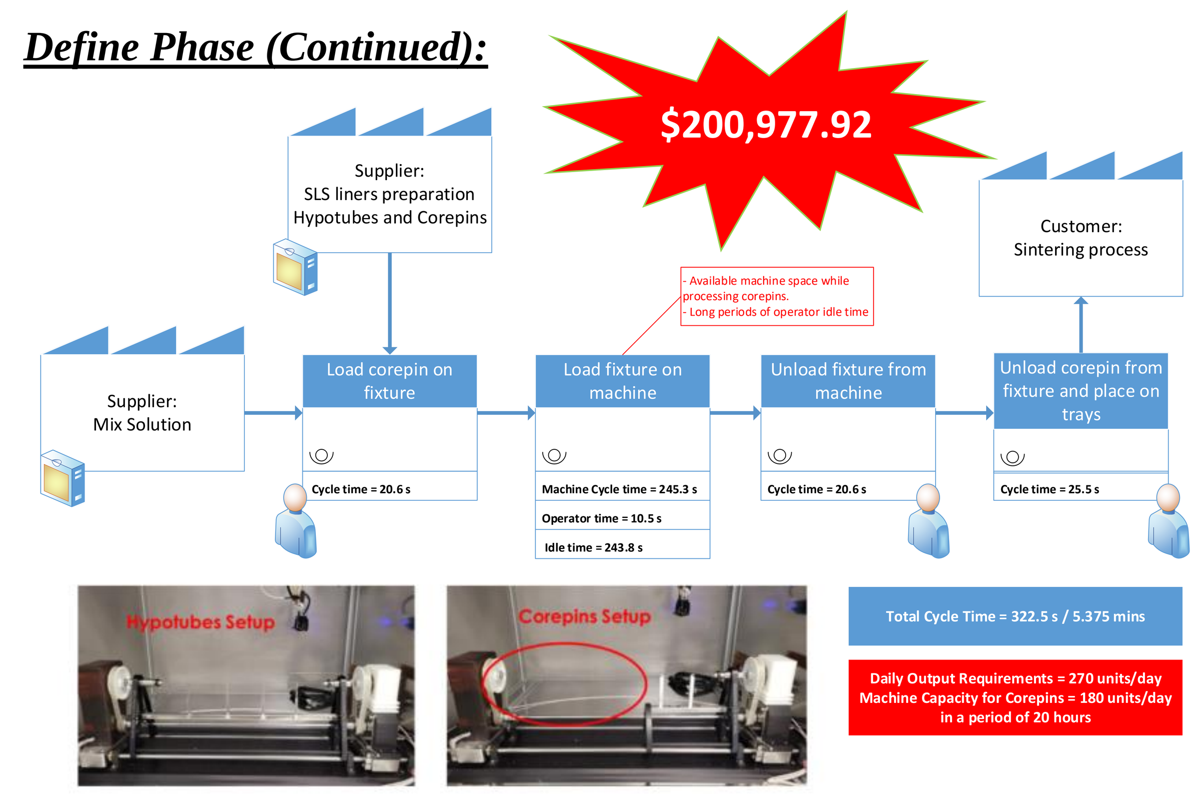
Measure Phase:

- Process/equipment cycle time study and Values Stream Map.

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					

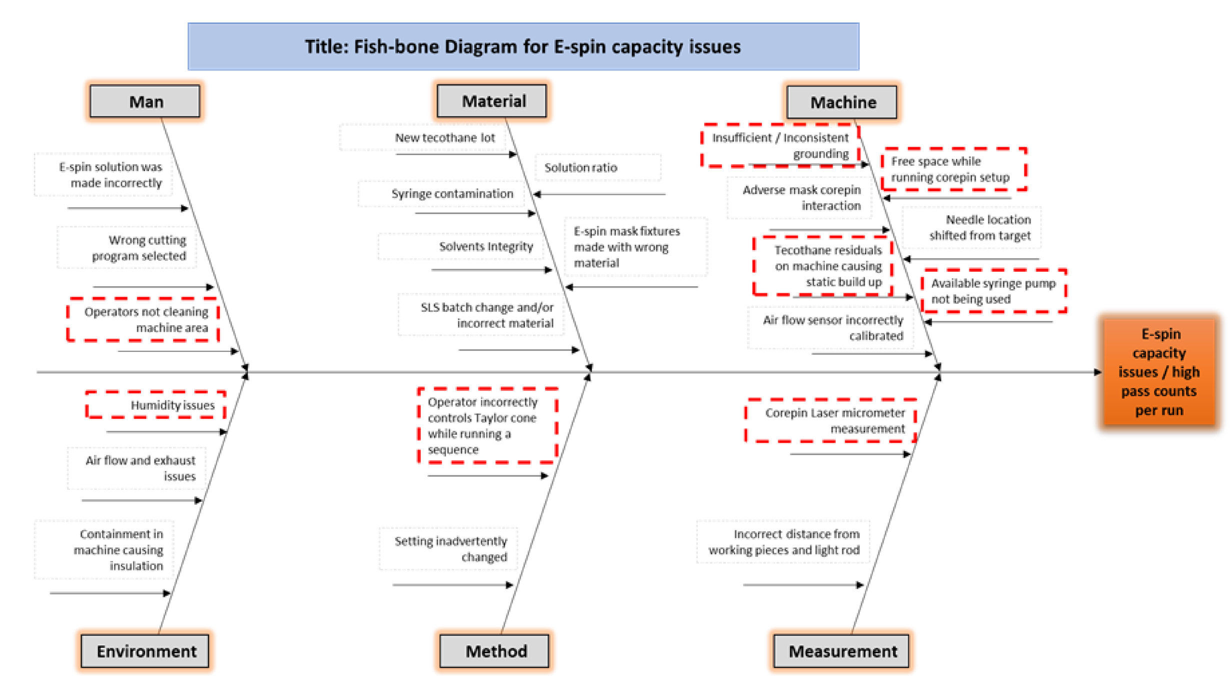
Results and Discussion (Cont.)

Define Phase (Continued):



Analyze Phase:

- Fish bone diagram and potential theories prioritization.



Improve Phase:

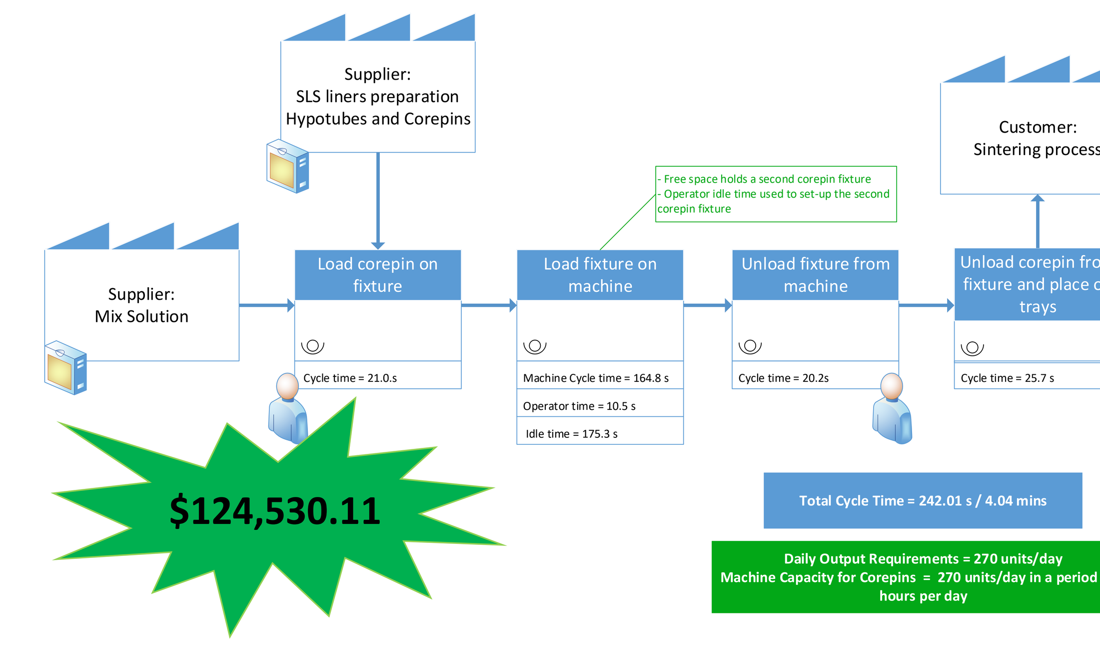
- Brainstorming sections to generate solutions ideas on multi-needle conversion.
- Validation and Implementations strategy for double needle fixture

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.

Results and Discussion (Cont.)

Control Phase:

- Operator trainings
- Improvement Validation against project goals and project savings calculations



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 in 2021.

Future Work

After the double nozzle implementation , the extended team will study and understand the effects double nozzle while running hypotubes setups.

Acknowledgements

Special Thanks to E-spin extended team: B. Sastre, H. Colón, J. Carmona, D. Wulfman, J. Nevarez and Boston Scientific Company

References

[1] Partheniadis, I., Nikolakakis, I., Laidmäe, I., & Heinämäki, J. (2020). A mini-review: needleless versus multi-needle electrospinning of nanofibers for pharmaceutical and biomedical applications. Processes, 8 (6), 673. https://www.mdpi.com/2227-9717/8/6/673

[2] Haitao, N., Hua, Z., & Hongxia, W. (2019) Chapter 1: Electrospinning: an advanced nanofiber production technology. Energy Harvesting Properties of Electrospun Nanofibers, 1- 44. https://iopscience.iop.org/book/978-0-7503-2005-4/chapter/bk978-0-7503-2005-4ch1