Design for Six Sigma Using DMADV for Implementing Sewing Machine

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Abstract *— This project focus on process design whose aim is to find credible bounding parameters for an industrial sewing machine with the intention to minimize production cost, speed up the process and assure an output of high-quality level. Design for Six Sigma (DFSS) was applied to structure a methodology that allows organizing and managing the process activities. This article shows the implementation of a problem-solving method (DMADV) to improve the performance level of the sewing process. The details of the research for the Six Sigma level process, statistical tools, data collection, factors and levels, response data transformation, experimental design, and the analysis are included in this paper.*

Key Terms *— Design of Experiments, DFSS, DMADV, Sewing Process.*

INTRODUCTION

In Becton Dickinson & Company of Humacao, Puerto Rico, the forecast for some products revealed an increment in volume demand for the FY 2019. Becton Dickinson is one of the largest global medical technology company. The company is engaged in the development, manufacture, and sale of medical devices, instrument systems, and reagents used by healthcare institutions, life science researchers, clinical laboratories, the pharmaceutical industry, and the general public. BD Humacao facility is located at the East of Puerto Rico, an installation which previously was C.R. Bard Company. In 2017, Becton Dickinson welcomed C. R. Bard and its products into the Interventional Specialties family. This facility is a leading manufacturer engaged in manufacturing, importing and exporting activities. A variety of Hernia repair products are manufactured at Becton Dickinson Interventional (BDI) Humacao, and the majority of these products are meshing which are produced through the use of sewing machines. These machines are used to sew two pieces together, create an orientation marker on the mesh, confine the memory ring, or make a pocket to ease placement and positioning, depending on the nature of the product.

Most of the machines used at BDI PR, Humacao facility, are obsolete on manufacturer's catalog, as these versions are dated from December 1997 to December 2007. Since newer versions are available, some of the critical components are obsolete, limiting BDI PR on the level of repairs and adjustments that can be performed. The company has the need to apply a lean project that can help reduce waste. With the replacement of obsolete sewing machines, the company expects to reduce manufacturing issues and meet product demand without incurring in Overtime hours.

PROBLEM STATEMENT

BDI Humacao, Puerto Rico, 3D Max Manufacturing line current output is not fulfilling demand requirements. The products manufactured are 3D Max Regular Mesh and 3D Max Light Mesh in sizes of Medium, Large, and Extra Large for left and right orientation.

The current Mfg. Line of 3D Max product family possesses three Industrial Sewing Machines. The wear of machine components no longer available for replacement is resulting in a high amount of scrap and downtime and is affecting the line efficiency. The amount of Corrective Maintenance (CM) Work Orders generated to fix the machines by BDI technicians during 2018 was 42. These are above the regular Preventive Maintenance Work Orders performed along the year. The project goal is to eliminate or at least reduce 80% of the actual CM Work Orders generated and manufacturing interruptions. This improvement will represent a production increase of 20,394 units.

The manufacturing line of 3D Max produced a total of 932,807 end units for which 29,776-unit were scrapped per the material report of FY 2018; 56% of the scraps are related to sewing defects. Besides, the product demand increased for FY 2019 and still sustained per forecast for FY 2010. The company has invested in three new versions of industrial sewing machines to replace the legacy machines. The intent of acquiring these machines is to minimize the risk of business interruptions, improve efficiency, and reduce scrap.

PROBLEM DESCRIPTION

3D Max Mesh product is constructed of knitted polypropylene monofilaments which are used to reinforce soft tissue where weakness exists, in the repair of hernia and chest wall defects. They are designed to conform to the inguinal anatomy and retains its shape following laparoscopic introduction. All 3D Max products have a Medial Mark letter as an “M” with an arrow below pointing left or right to reference the physician the orientation in which the mesh should be positioned during the insertion. This Medial Mark is made during the 3D Max manufacturing process through the use of sewing machines.

The sewing is one of the critical processes in the determination of compliance with productivity and quality of finished mesh products, and it is the most common way in BD Humacao to fabric the assembly in order to achieve the required seam during its manufacturing. The sewing thread is one of the crucial elements of the sewing process, and there is still no substitute for it.

The problem associated with sewing output variations is a combination of the thread material and machine properties that cause breakage in the needle thread during the recurrent sewing operation. The introduction of the new version of sewing machines involves high-speed sewing operations for a variety of 3D Max mesh product codes, which could improve production capacity. The selection criteria of the sewing thread become more stringent when sewing at a higher speed. An unbalanced tension imposed on the thread during the sewing process is the most crucial cause of thread breakage or unwanted seam. Currently, the sewing thread used to sew the Medial Marker into the mesh has a certain amount of elasticity and elongation controlled by the supplier, but it becomes overstretched during the manufacturing process when the tension system is high due to unbalanced tension forces. After sewing, the thread gets to start relaxation to recover its initial length and thus gathers up a seam. When the needle thread is subjected too much higher tension than the bobbin thread, it mainly contributes to an unwanted seam. Also, when there is too much tension applied within the system guide elements, it contributes to breakage in the needle thread.

The change of production volume per item suggested the application of a methodology that is able to discard the existing sewing machine processes and substitute them with radically new ones in terms of machine parameters, conditions, user interface, methods and raw materials as applicable. Design for Six Sigma (DFSS) can be a strategic methodology for designing a process capable of reaching Six Sigma levels. The major goal of DFSS is to design it right the first time to avoid painful downstream experiences [1]. This project emphasis on the implementation of the new sewing machines using the DMADV approach, a Six Sigma tool for the design of further process characterization. The utilization of the traditional Six Sigma approach DMAIC focuses on constant and continuous incremental improvements. In this case, it was felt that the best solution was to apply a methodology that could analyze and review historical data and information leading to redesigning and modifying the system towards Six Sigma levels. For this reason, DFSS represented an appropriate strategy that would satisfy the company needs using DMADV approach. This methodology involves phases of Define, Measure, Analyze, Design, and Verify which are used to design processes for optimum performance. The key methodology concept is to design new processes and avoid defects with a high-performance level [2]. The DMADV roadmap steps for this project consists of the following:

The goal of the Define phase is to develop a clear definition of the project that includes economic impact, risk management plans, and possible organizational change activities. It is also important to draft a project charter that highlights business care, involved processes, establish the problem, set the scope, identify metrics, and set project goals. A clear definition of the project will be established in this step. Every strategy and goal will be aligned with the expectations of the company. All deliverables of the define phase are a list of critical aspects (CTQs) that are the input of the measurement step.

In the Measure phase, the factors that are linked to quality, which leads to CTQs, will be measured. Scatter Plots and Control Charts will be used to measure the thread tension behavior and identify the critical design parameters.

Cause and effect analysis will be conducted to Analyze the process options. Once the values for these factors are known, the process options will be analyzed with an effective Design of Experiment (DOE) approach to identify the optimal combination and develop the best possible design.

During the design phase, DOE will be conducted in an effort to have a better understanding of how the different variables encounter in the sewing process can affect the seam of a component. It is imperative to conduct a Design of Experiment that helps find the proper parameters combination and then determine the optimal settings of the critical-to-quality factors in the screening process. By achieving optimal settings, the process can be verified through a process qualification.

In the Verify phase, a dry run and output check will be performed for the parameters designed to ensure that this change is sustainable before proceeding with the process qualification.

RESEARCH OBJECTIVES

The aim of this project consists of implementing two new version of sewing machines for the Manufacturing Line of 3D Max Mesh products with the objective of minimizing the risk of business interruptions, improve efficiency, and reduce scrap. A machine process characterization will be developed to establish new operational parameters based on statistical study and analysis results. The implementation will be handled through effective process validation to contribute significantly to assuring product quality.

RESEARCH CONTRIBUTION

The project goal is to reduce scraps and the number of Work Orders for Corrective Maintenance that are generated due to a mechanical malfunction of the sewing machines. It is understood that the line will have improvement opportunities after the new sewing machine implementations. Upon the completion of this project in BDI Humacao facility, several contributions will rise for the company.

- Reduce the potential problems of scraps during the sewing process.
- Less impact on material expenses.
- Reduce equipment downtime.
- Meet production demands.
- Opportunities to rebalance the 3D Max Mfg. Line after implementation.
- This study could be used as model to other sewing machines within the same plant.

DEFINE PHASE

The core business of the company with 3D Max Manufacturing line is the creation of three-dimensional anatomically shaped pre-formed polypropylene mesh for different profiles (Medium, Large, and Extra Large). As part of the outcome, the Medial Marker sewn to the 3D Max Mesh is made with the use of the sewing machine which is one of the main complex systems. The main technical customer requirements are dimensional tolerance satisfaction and the typical appearance of "M" letter (Medial Marker) with its arrow pointing left or right for medical orientation without deformation, loose thread, or general damage on the mesh. The first step of the project was a global review of the manufacturing system in order to understand the main Critical to Quality characteristics. Through brainstorming and using the useful tool of Process FMEA, it was possible to identify that adequate threading in the sewing machine represents the main process on which the project needs to focus on increasing the performance levels.

The main complicity of the sewing system is stabilizing tension. Thread tension is defined by four devices that put a varying amount of strength within upper and lower tensions to ensure that the same amount of thread flows simultaneously from the needle and the bobbin, producing a symmetrical stitch. These devices control the threading during operation through thread guides, tension discs, two manual tension to regulate the upper thread, and bobbin-case which is the only device at the lower thread. The combination of these devices determines how well balanced are the tensions to obtain a proper stitched on both sides of the mesh.

In this phase, several keys of the sewing process were defined by verifying the performance level and mapping the main activities. Figure 1 shows a SIPOC tool to highlight the main inputs of the sewing process.

The quality of the response (Medial Marker) is defined by different factors, in particular, the upper tension which depends on several elements, the lower tension, thread material, and sewing speed. In fact, a variety of problems can emerge during sewing process due to imbalance tension system such as needle thread breakage, bobbin thread breakage, skipped stitches, seam puckering, or loops/variable stitching.

Suppliers	Inputs	Process	Output	Customers
➢Blue Polypropylene Monofilament ➢Regular Mesh Cut ➢Light Mesh Cut ➢220VAC ± 10% ➢Compressed Air ≥ 0.5 MPa	➢Sewing Speed ➢Lower Tension ➢Upper Primary Tension Controller ➢Upper Secondary Tension Controller ➢Threading	Sewing	➢Light Mesh with Medial Marker ➢Light Mesh with Medial Marker	➢Operator ➢Documentation

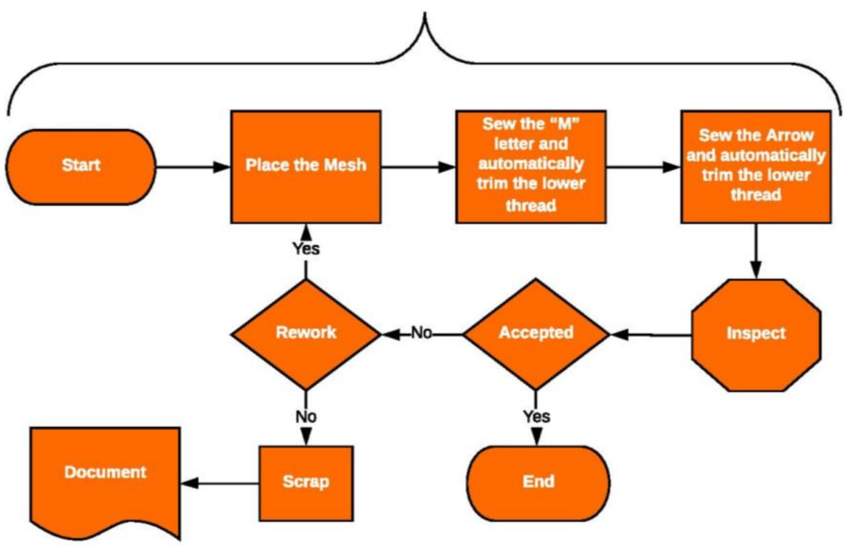

Figure 1
Sewing Process SIPOC

A rigorous definition of the VOC of the sewing process represented a fundamental step to understand 'how' the sewing process may be modified and redesigned. Using internal company reports of scrap reasons were collected to develop the main defect categories as shown in table 1.

Table 1
VOC vs. VOP

Defect Category	*Scraps*	*Defect %*
Out of alignment	180	1%
Sewing Defect	4895	36%
Bad Cut	2871	21%
Bad Seal	1346	10%
Broken	643	5%
Broken Edge Seal	1281	9%
Wrinkles	15	0%
Unit Felt on Floor	334	2%
Deformation	96	1%
Particle	1839	14%
Total	13500	100%

MEASURE PHASE

The second step of the DMADV roadmap was the Measure phase. Based on a production volume of 1.1 million of meshes from January 2018 to March 2019, the Critical to Customer (CTCs) features were highlighted. A weighted Pareto chart was plotted to track defect occurrence and the cost to rework as shown in figure 2.

However, replacing the sewing machine with the new version, the company could reduce a significant part of costs covering scraps and labor due to equipment malfunction/downtime. The sewing machine system is a direct driver-programmable electronic pattern tacker sewer with cylinder bed. The new machines come with a digital thread tension control which is replacing the old tension release system (manual tension adjustment). The digital tension is adjusted by the operator through a functional LCD touch screen/panel which has a feature to add or subtract tension in gram-force (gf) to the primary upper thread and is controlled by a solenoid actuated valve when activated meanwhile the tension release system is manually adjusted through a knob nut that applies resistance to the tension disk. In order to deploy an effective performance-level analysis, it was important to evaluate the behavior of the tension at different set points to qualitatively identify the main critical aspects of the threading process. For an effective measurement activity, it was necessary to acquire an accurate tension meter system that store readings and export data collect.

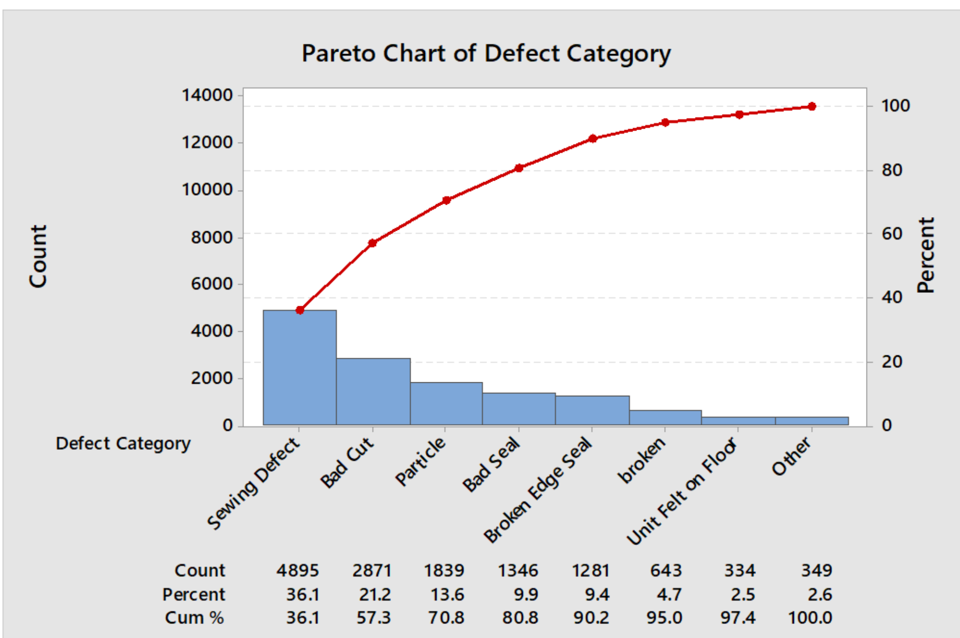

Figure 2
Pareto Diagram of Defect Categories

This data was studied in order to discover potential instability sources or similarities between the new tension mechanisms vs. the old one. After the evaluation, it was found that the digital tension is not adequate to obtain optimal yield for the sewing process. As improvement actions and suggestions, the system was changed to manual tension. Another event considered for evaluation was the thread diameter variation along its single continuous filament which also affects the tension of the sewing process. The thickness of the thread must be between 0.0063” and 0.0080” as per specification requirements of the blue polypropylene monofilament for BDI products. Four thread spools were retrieved from different lots to observe how consistent the thickness along the thread. Every thread spool grouped a series of thirty observations. It was common practice to collect the diameter values on every linear foot of thread to assess the thickness behavior and capability on those samples.

When the observation period ended, the data was gathered together, managed and analyzed using Minitab statistical software. In figure 3, the variables on the multiple probability plots show how the data can be considered as normally distributed for each individual lot. The p-values are greater than the significance level of 0.05 confirming that data points are relatively close to the fitted normal distribution line [3].

ANALYSIS PHASE

The first step of the analysis was a critical assessment of the possible variability sources of the thread tension using a Cause and Effect diagram [4]. Applying 6M’s Method in a fish-bone diagram divided the different variability sources into six classes: Method, Measurement, Machine, Material, Man and Mother Nature. For every class, a number of defect causes were listed on which to focus on in order to obtain an immediate improvement:

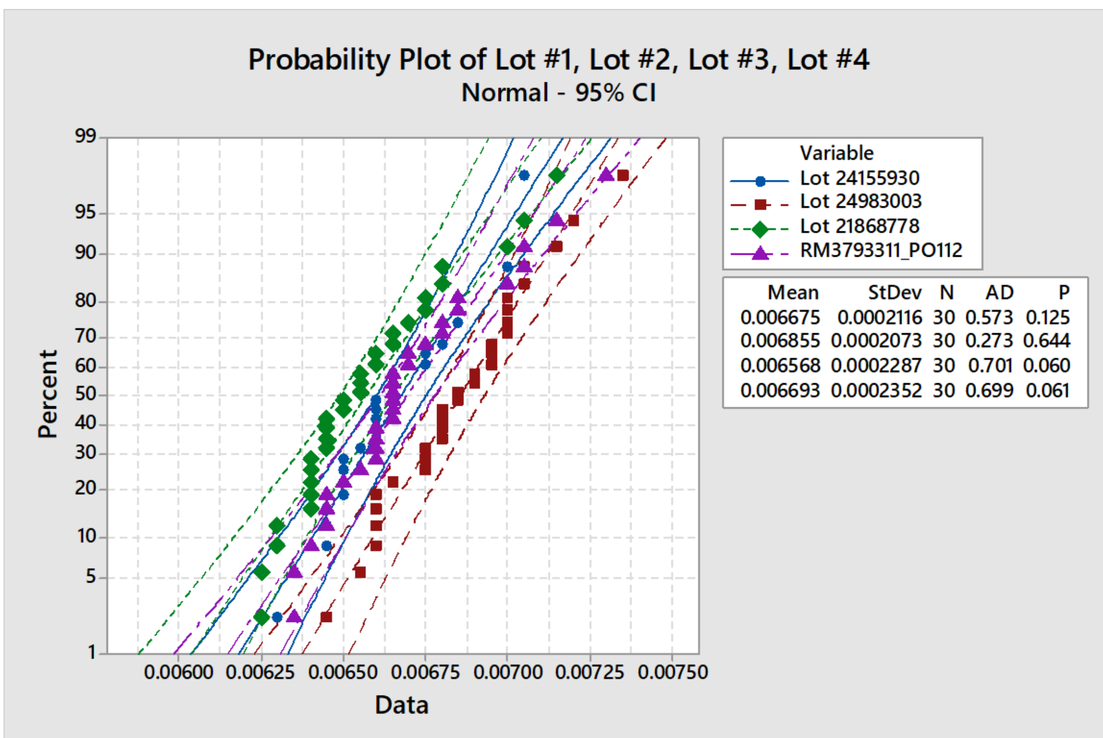

Figure 3
Fitted Distribution Line of Each Subgroup

- **Machine:** It was determined that air pressure for the work-clamp is not a significant contributor to the variation since its function is to hold the mesh in place while Medial Marker is sewn. Nonetheless, air pressure is necessary for maintaining the mesh in position for a smooth stitched. The functionality of the sewing machine components requires to have the equipment in its lubrication state using food grade oil since the thread is continuously in contact with the threading guide elements are near the lubrication points which are in connection with the thread and could lead to an impact in patients.
- **Method:** The setting of the thread tension parameters has a fundamental effect on the performance level of the sewing process. The tension system plays several contributions to variability. The preferred tension in grams-force should be that which provides acceptable sewn without interruptions during the sewing process, allowing the shortest possible cycle time. At high tension forces around the system, final sewn brings acceptable appearance, but interruptions are more frequent during the sewing process. At low tension forces running within the system, stitched turn out to be loose. It is also important to consider that an unbalance tension system (upper tension ≠ bottom tensions), wrinkles at one face of the mesh becomes more often. After testing several settings, it was determined that these factors play a primary role to obtain acceptable Medial Marker appearance.
- **Materials:** The regular mesh is made with a closer hole pattern than the light mesh which makes it stronger and eases the sewn of the Medial Marker appearance. Thus, at higher tension during sewing could result in deformity aspect. In addition, the non-sterile blue unannealed polypropylene suture monofilament, which is a fiber thread raw material, is fundamental in order to satisfy the customer requirements. The thickness of this thread with blue appearance could influence the other process parameters and therefore the performance level of the system. After measuring the behavior of the thread thickness along its path, it was indisputable the significant contribution on the variability. For this reason, a further study of the supplier casting process could be important to minimize this variation.
- **Manpower:** The knowledge of the threading process, operators could impact on the tension force setup. In fact, they could intervene in order to change the process parameters if the tension did not satisfy the requirements. A definition of a clear and rigorous procedure will be necessary with the implementation of the new tension measuring instrumentation.
- **Measurements:** The current measurement system (Force Gauge) is unacceptable for the new process development since it could affect the performance level of the complete tension system reliability. Therefore, a Tension Meter with Motorized Take-Up was acquired for the tension set up in the sewing machine.
- **Mother Nature:** The last important aspect of the sewing process was the presence of vibrancy of the thread during the sewing process. This fact is due to the threading system. Nonetheless, the equipment is located in a controlled environment room.

First of all, the quantitative analysis began by stratifying data collected during testing different tension force levels, grouping with different criteria and maintaining at least one factor unaltered. Thus, considering the sewing speed, upper tension, bobbin tension, and take up spring distance as the potentially relevant factors that could influence the tension and outcome process capability, an Exploratory Data Analysis (EDA) has been performed. For every group of data arranged, the main statistics, the distribution assessment have been collected. The goal of this phase was to quantify the main factors impacting on the process variability and to set the process parameters in order to increase the process capability.

EDA is a collection of qualitative and quantitative tools, graphs and methods used to obtain useful information from a set of data [5]. In this analysis, EDA refers to a qualitative and visual representation of the data, a collection of process statistics, up to a modeling attempt through analysis of variance.

The thread thickness data was analyzed, and it was found a significance variability within batch with a p-value of 0.001.

Based on this assessment, it was decided to set measurable tensions as factors rather than configurations of the nut turns for each tension device or LCD panel tension configuration. Every factor varies between levels; according to the company experience with the legacy sewing system and manufacturer technician suggestions, the thread tension system balanced near the 100 gram-force shall provide a proper stitch. However, after several trials of setting to set factor levels, the Sewing Speed can vary between 1200 rpm (low) and 1800 rpm (high), the Bobbin Tension varies in a range between 55 gf (low) and 75 gf (high). The Upper Tension consists of two devices at top and bottom controlled through the use of knobs which allow manual strength adjustments; the bottom tension can vary from 80 gf (low) and 110 gf (high), the top tension knob varies in a range between 85 gf (low) and 155 gf (high).

The Take-up Spring was determined to be adjusted as a common practice since its functionality is required to holds the thread as the needle comes down into the fabric until the eye of the needle penetrates the mesh. It prevents the thread from flopping in front of the needle. Also, the Take-up Spring acts like a little shock absorber while the stitch is being formed.

A Screening Design of Experiment (DOE) was conducted to identify the relationship between five (5) factors that may produce any failure during the sewing process and determine exactly which of the factors significantly affects the Medial Marker sewn [6]. The ½ fractional model involved two replicates for a total of 32 runs.

Based on the outcome of the sewing operation are attribute data that is binary, and whether the result is Pass/Fail decision by visual inspection, the Transform Proportion approach was used as related variable measurement data since DOE does not analyze attribute data [7]. Therefore, each data gathered was converted to ration of acceptance. Thus, the closer to high value represents the acceptance level. In order to increase the accuracy of the experiment, each treatment was replicated twenty (20) times to report variable data for each treatment and plot the values to run the experiment and identify significant factor changes; refer to table 2 for data conversion results. The data fitted a normal distribution with a p-value of 0.100 for the DOE analysis.

Figure 4 shows the analysis of variance (ANOVA) providing a summary of the main effects and interactions [8].

For statistical tests, the p-values are quoted; the p-values lesser than 0.05 confirms a significant effect.

Through the source of main effects, the results indicate that the Press Foot effect is statistically significant at 0.05 α-level; thus, implies that the sewing output is affected by the Press Foot negatively as an independent variable. It means that when the Press Foot height is increased, the level of acceptance for the Medial marker sewn (response) decreases. Besides, in 2-way interaction analysis, the results indicate that Sewing Speed has a positive significant interaction with the Bottom Tension as well the Top Tension with the Press Foot; when they change from the low level to the high level of its factor, the response increases. The Press Foot has a dramatically more effect than the other factors. This analysis suggests that the set-point for the press Foot at 3 mm will provide a high proportion of acceptance (i.e., a high proportion of acceptance, or low proportion of rejections).

Table 2
Layout of Result with Proportion Transformation

Sanmple	Factors					Output with 20 Replicates																				Proportion (p)
Run No.	Sewing Speed (rpm)	Bobbin Tension (gf)	Top Tension (gf)	Bottom Tension (gf)	Press Foot Height (mm)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	
1	1200	55	85	80	4	NGO	NGO	GO	GO	NGO	NGO	GO	NGO	NGO	GO	NGO	GO	GO	GO	GO	NGO	GO	GO	GO	GO	0.60
2	1800	55	85	80	3	GO	NGO	NGO	NGO	GO	NGO	NGO	GO	NGO	GO	GO	GO	NGO	NGO	NGO	NGO	GO	NGO	GO	NGO	0.40
3	1200	75	85	80	3	GO	GO	GO	GO	GO	GO	GO	GO	NGO	GO	GO	GO	GO	GO	GO	GO	GO	GO	GO	GO	0.95
4	1800	75	85	80	4	GO	NGO	NGO	NGO	GO	GO	GO	GO	GO	GO	GO	GO	NGO	NGO	NGO	NGO	NGO	GO	NGO	NGO	0.50
5	1200	55	155	80	3	NGO	GO	NGO	NGO	NGO	NGO	NGO	GO	GO	NGO	NGO	GO	GO	NGO	NGO	NGO	NGO	GO	NGO	GO	0.35
6	1800	55	155	80	4	NGO	GO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	GO	NGO	NGO	GO	NGO	NGO	NGO	GO	NGO	0.20
7	1200	75	155	80	4	NGO	NGO	NGO	NGO	NGO	NGO	NGO	GO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	GO	GO	NGO	NGO	0.15
8	1800	75	155	80	3	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	GO	NGO	NGO	GO	GO	NGO	GO	GO	NGO	NGO	GO	NGO	0.30
9	1200	55	85	110	3	GO	GO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	GO	0.15
10	1800	55	85	110	4	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	0.00
11	1200	75	85	110	4	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	0.00
12	1800	75	85	110	3	GO	NGO	GO	GO	GO	NGO	GO	GO	NGO	GO	NGO	NGO	GO	GO	NGO	GO	GO	GO	GO	GO	0.70
13	1200	55	155	110	4	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	GO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	GO	NGO	NGO	GO	0.15
14	1800	55	155	110	3	GO	NGO	GO	NGO	GO	NGO	NGO	GO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	GO	NGO	NGO	GO	NGO	0.30
15	1200	75	155	110	3	NGO	NGO	NGO	NGO	NGO	GO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	GO	NGO	GO	GO	NGO	0.20
16	1800	75	155	110	4	GO	NGO	NGO	NGO	NGO	NGO	NGO	GO	NGO	GO	GO	NGO	NGO	NGO	GO	GO	GO	NGO	NGO	NGO	0.35
17	1200	55	85	80	4	GO	NGO	NGO	NGO	GO	NGO	GO	GO	GO	GO	NGO	NGO	GO	NGO	GO	NGO	NGO	NGO	NGO	NGO	0.40
18	1800	55	85	80	3	NGO	GO	NGO	GO	GO	GO	GO	GO	GO	NGO	NGO	NGO	GO	GO	GO	NGO	NGO	NGO	NGO	NGO	0.50
19	1200	75	85	80	3	NGO	GO	GO	GO	GO	GO	GO	NGO	NGO	GO	NGO	NGO	NGO	GO	GO	GO	GO	GO	GO	GO	0.70
20	1800	75	85	80	4	NGO	GO	GO	GO	GO	NGO	NGO	GO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	GO	NGO	NGO	NGO	NGO	0.30
21	1200	55	155	80	3	GO	NGO	GO	GO	NGO	NGO	GO	NGO	NGO	GO	GO	NGO	GO	NGO	NGO	NGO	NGO	NGO	GO	GO	0.45
22	1800	55	155	80	4	GO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	GO	NGO	GO	NGO	NGO	NGO	NGO	GO	NGO	GO	0.25
23	1200	75	155	80	4	GO	GO	NGO	GO	NGO	NGO	NGO	NGO	GO	NGO	NGO	GO	GO	GO	GO	NGO	NGO	GO	NGO	NGO	0.45
24	1800	75	155	80	3	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	GO	NGO	NGO	GO	NGO	GO	NGO	NGO	NGO	GO	NGO	0.20
25	1200	55	85	110	3	GO	NGO	GO	GO	GO	GO	GO	GO	NGO	GO	GO	GO	NGO	NGO	GO	GO	NGO	GO	GO	NGO	0.70
26	1800	55	85	110	4	NGO	NGO	GO	GO	GO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	0.15
27	1200	75	85	110	4	GO	NGO	NGO	GO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	GO	NGO	NGO	NGO	NGO	GO	0.20
28	1800	75	85	110	3	GO	GO	NGO	GO	GO	NGO	GO	GO	GO	GO	GO	GO	GO	GO	GO	GO	GO	GO	NGO	NGO	0.80
29	1200	55	155	110	4	NGO	NGO	NGO	GO	GO	NGO	GO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	NGO	0.15
30	1800	55	155	110	3	NGO	GO	GO	NGO	GO	GO	NGO	GO	NGO	NGO	NGO	GO	GO	NGO	NGO	GO	GO	NGO	GO	GO	0.55
31	1200	75	155	110	3	GO	GO	GO	GO	NGO	NGO	GO	GO	GO	GO	GO	GO	GO	NGO	NGO	GO	GO	NGO	NGO	GO	0.70
32	1800	75	155	110	4	NGO	NGO	GO	NGO	GO	GO	GO	GO	GO	NGO	GO	GO	GO	GO	NGO	GO	GO	GO	NGO	GO	0.70

Factorial Fit: Response versus Sewing Speed, Bobbin Tension, ...

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Estimated Effects and Coefficients for Response (coded units)

Term                           Effect     Coef  SE Coef      T      P
Constant                                0.3906  0.03240  12.06  0.000
Sewing Speed                  -0.0063  -0.0031  0.03240  -0.10  0.924
Bobbin Tension                 0.1187   0.0594  0.03240   1.83  0.086
Top Tension                   -0.1000  -0.0500  0.03240  -1.54  0.142
Bottom Tension                -0.0562  -0.0281  0.03240  -0.87  0.398
Press Foot                    -0.2125  -0.1062  0.03240  -3.28  0.005
Sewing Speed*Bobbin Tension    0.0688   0.0344  0.03240   1.06  0.304
Sewing Speed*Top Tension       0.0375   0.0187  0.03240   0.58  0.571
Sewing Speed*Bottom Tension    0.1687   0.0844  0.03240   2.60  0.019
Sewing Speed*Press Foot        0.0500   0.0250  0.03240   0.77  0.452
Bobbin Tension*Top Tension    -0.0375  -0.0188  0.03240  -0.58  0.571
Bobbin Tension*Bottom Tension  0.0687   0.0344  0.03240   1.06  0.304
Bobbin Tension*Press Foot     -0.0250  -0.0125  0.03240  -0.39  0.705
Top Tension*Bottom Tension     0.1500   0.0750  0.03240   2.31  0.034
Top Tension*Press Foot         0.1312   0.0656  0.03240   2.03  0.060
Bottom Tension*Press Foot     -0.0875  -0.0437  0.03240  -1.35  0.196


S = 0.183286     PRESS = 2.15
R-Sq = 70.90%    R-Sq(pred) = 0.00%    R-Sq(adj) = 43.62%
```

Figure 4
ANOVA with Significant Effects

It can be interpreted that an optimal response can be found near to the low setting of Press Foot, Top Tension, and Bottom Tension.

This kind of analysis allowed to understand quantitatively how the tension measurement varies and why and how the process capability can be influenced as a consequence. The Analyze phase output provided useful suggestions to be implemented in the Design phase. In fact, looking at the main effects and interactions for every combination of factors, an optimization design was planned in order to improve the overall sewing process.

DESIGN & VERIFY

The design phase considered a renewal of the process, strictly based on the results previously achieved.

A response optimizer for a target value of 0.8 was predicted (figure 5). After assessing the plots, it was determined that the highest yield of the Medial Marker acceptance is obtained when the Press Foot is at 3 mm height and sewing at lower tensions. Although the Sewing Speed was an insignificant main effect, it cannot be removed from the model, since its main effect is part of the significant interaction with Bottom Tension.

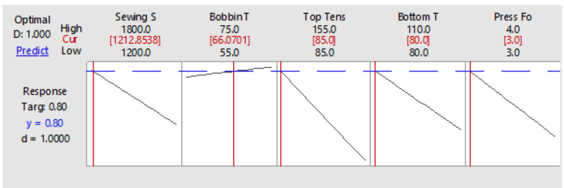

Figure 5
Optimization Plot

The results and analyses suggested that changing the "settings" of the Press Foot, Top Tension, and Bobbin Tension it is possible to obtain a response meanly close to a better desirable response. The factorial design model was reduced and structured as shown in table 3 to keep the response close to the target value.

Table 3
Proposed Optimization

		Level	
		Low	***High***
Factors	Sewing Speed (rpm)	1200	1800
	Bobbin Tension (gf)	**54**	**68**
	Top Tension (gf)	**85**	**120**
	Bottom Tension (gf)	80	110

In the Design phase, the critical process variables from the previous analysis were imposed. In this manner, it has been possible to build another experiment by removing one variable factor and setting two of the four factors remaining [8]. Based on the previous DOE exercise, it was decided to involve the two Light Mesh and Regular Mesh as blocks, since variation could be significant and determine if separate optimizations will be required. For optimal design, the structure of the experiment design of a full factorial will be modeled with two replicates and two blocks.

This design is expected to provide excellent information concerning the main effects and two-factor interactions. After executing the DOE, the response values will be analyzed by comparing the new design with the baseline concept.

In the Verify phase, the best optimal design will be validated to confirm that the process parameter windows that were developed through the process characterization of the Sewing Machine produce the expected output. This is done to make sure that the design meets the customer's requirements and to monitor scraps and downtime during the manufacture of 3D Max Regular Mesh and Light Mesh.

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