Quality Improvement in a Medical Device Manufacturing Process Applying Six Sigma Tools

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Abstract — *The current manufacturing process of a medical device product has great opportunities on scrap percent reduction, which has been impacting the material and labor costs of the product, as well as in defects per million (DPMs) reduction, to improve the quality of this product. The current scrap percent has been affecting the production yield and complaints from clients (surgeons) have been increasing during the last Fiscal Year. The Six Sigma structure DMAIC: Define, Measure, Analyze, Improve, and Control, will be the key for the success of this project. The expected benefits are the evaluation, recommendation, and implementation of any opportunity of quality improvement that results in a positive impact to the clients at a low cost of production for the company. The main research contribution is that this project provides the customers (surgeons and their patients) an instrument that always actuate as established in the specifications to save humans lives.*

Key Terms *— Medical Devices, Process Optimization, Quality Improvement, Six Sigma.*

PROBLEM STATEMENT

The current manufacturing process of a medical device product has great opportunities on scrap percent reduction, which has been impacting the material and labor costs of the product, as well as in defects per million (DPMs) reduction, to improve the quality of this product.

The objective of this project is to use Six Sigma tools to reduce:

- The current Scrap by 40 percent.
    - Baseline: 10 percent.
    - Goal: 6 percent.
- The current Cost per unit (material and labor costs).
    - Baseline: $9.92 per unit
    - Goal: $9.49 per unit.
    - Cost Reduction: $0.43 per unit.
    - $103,000 on annualized cost savings.
- The current DPMs by 50% for the following major offender defects:
    - Advance staples and improper gluing.
    - DPMs baseline: 60,170.
    - DPMs goal: 30,085.

BACKGROUND

In this section, basic information on Medical Devices and Six Sigma is presented for a better understanding of the project.

Medical Device

A medical device, according to the U.S. Food and Drug Administration (FDA), is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.
- Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes [2].

The medical device process which will be improved using the Six Sigma tools is described as follow:

- Instrument description - single use loading unit (SULU) places two, double staggered rows of stainless steel staples and simultaneously divides the tissue between the two, double rows.
- Instrument indications – have application in abdominal, gynecological, pediatric and thoracic surgery for resection, transaction and creation of anastomoses.

A resection is a type of abdominal surgery that is commonly used to treat patients with Crohn's disease (CD). In this type of surgery, a portion of the large or small intestine is removed, and the two healthy ends are reattached. The following picture illustrates an intestine affected by a tumor.

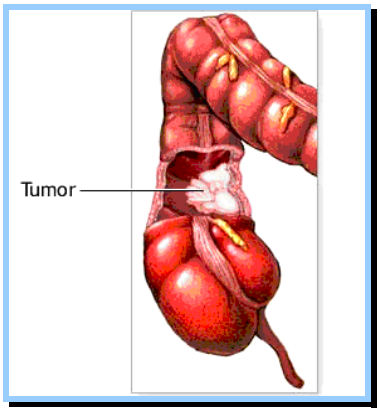

Figure 1
Intestine Affected by a Tumor

Anastomosis is the connection of two structures, results from trauma or disease and may involve veins, arteries, or intestines. Figure 2 illustrates an intestinal anastomosis.

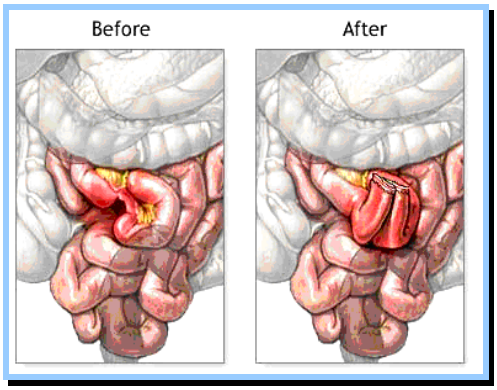

Figure 2
Intestinal Anastomosis

Six Sigma

Six Sigma was originally developed as a set of practices designed to improve manufacturing processes and eliminate defects, but its application was subsequently extended to other types of business processes as well. The particulars of the methodology were first formulated by Bill Smith at Motorola in 1986.

Six Sigma was heavily inspired by six preceding decades of quality improvement methodologies such as quality control, TQM, and Zero Defects, based on the work of pioneers such as Shewhart, Deming, Juran, Ishikawa, Taguchi and others. Like its predecessors, Six Sigma asserts that:

- Continuous efforts to achieve stable and predictable process results as reduced process variation are of vital importance to business success.
- Manufacturing and business processes have characteristics that can be measured, analyzed, improved, and controlled.
- Achieving sustained quality improvement requires commitment from the entire organization, particularly from top-level management [3].

The DMAIC methodology includes the following five steps; Define, Measure, Analyze, Improve, and Control. Some information regarding each step is presented in the following section.

- Define: is the first step in the process. In this step, it is important to define specific goals in achieving outcomes that are consistent with both the customers' demands and the own business's strategy. In essence, lay down a road map for accomplishment.
- Measure: In order to determine whether or not defects have been reduced, a base measurement is needed. In this step, accurate measurements must be made and relevant data must be

collected so that future comparisons can be measured to determine whether or not defects have been reduced.

- Analyze: Analysis is extremely important to determine relationships and the factors of causality. If trying to understand how to fix a problem, cause and effect is extremely necessary and must be considered.
- Improve: Making improvements or optimizing processes based on measurements and analysis can ensure that defects are lowered and processes are streamlined.
- Control: This is the last step in the DMAIC methodology. Control ensures that any variances stand out and are corrected before they can influence a process negatively causing defects. Controls can be in the form of pilot runs to determine if the processes are capable and then once data is collected, a process can transition into standard production. However, continued measurement and analysis must ensue to keep processes on track and free of defects below the Six Sigma limit. [1]

The following picture illustrates the five phases of DMAIC methodology.

Figure 3
DMAIC Methodology

Other important definitions highly associated with the process performance are described below.

- DPMs – in process improvement efforts, defects per million (DPMs) is a measure of process performance. It is defined as:

  DPMs = Number of defects X 1,000,000 / Number of units

- Defect – is a nonconformity or departure of a quality characteristic from its intended level or state [1].
- Defective – is a nonconforming item that contains at least one defect or has a combination of several imperfections causing the unit not to satisfy its intended requirements [1].
- Scrap Factor – is the percentage of components or materials destroyed or ruined during manufacturing or processing operations [1].
- Six Sigma – is a term coined by the Motorola Company that emphasizes the improvement of a process for the purpose of reducing variability and optimizing it. The following picture illustrates the sigma levels [1].

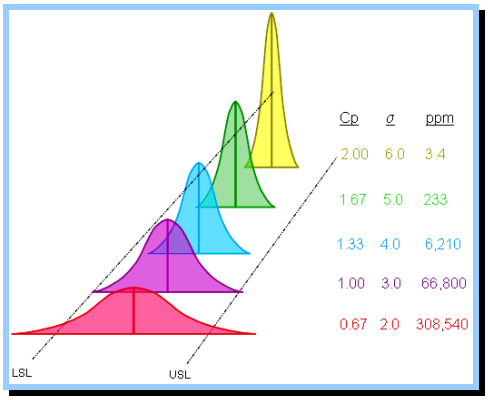

Figure 4
Six Sigma Levels

PROJECT METHODOLOGY

The methodology to be used during the execution of this project to achieve the objectives will be the DMAIC structure. The different tools that will be used in each one of the DMAIC phases is presented next.

Phase I – Define

- Project Charter – this document will describe the process, problem description, project objectives, metrics, business results, team members, benefits to external customers, required budget, and schedule.

- Voice of the customer (VOC) - describes the internal customers' needs and their perceptions of the manufacturing process. The main tool to be used is interviews.
- Project Y's – overall description of key process input variables (KPIV) and key process output variables (KPOV).

Phase II – Measure

- SIPOC Diagram – supplier, inputs, process, outputs customer diagram that gives a snapshot of work flows, where the process aspect of the diagram consists of only four to seven blocks.
- Process Map – path of steps of work used to produce the medical device. Helpful to identify opportunities for improvement, key process input variables (KPIVs), and key process output variables (KPOVs) and used as input during the development of the cause and effect matrix.
- Cause and Effect Matrix – with this technique possible causes from materials, equipment, methods, and personnel will be identified. After identified KPIVs and KPOVs the cause and effect matrix will help to prioritize the importance of KPIVs.
- Pareto Chart – graphical technique that will be used to quantify problems so that the effort can be expended in fixing the "vital few". It will help to identify the source of chronic problems and the common causes in medical device process.
- Failure Mode and Effect Analysis (FMEA) – analytical approach directed toward problem prevention through the prioritization of potential problems and their resolution.
- Kappa Test – the kappa (κ) test is a test of agreement, between experts and operators.
- Process Capability - Cpk, ratio which considers the shift of the mean relative to the central specification target.

Phase III – Analyze

- Histogram Analysis - a frequency diagram in which bars proportional in area to the class frequencies are erected on the horizontal axis.
- Probability Plot Analysis - to determine whether a particular distribution fits the data.
- Regression Plot Analysis - data collected from an experiment are used to empirically quantify through a mathematical model the relationship that exists between the response variable and influencing factors.
- Box Plot Analysis – box plots will be used to assess and compare sample distributions.
- Multivariable Test – chart that is constructed to display the variation within operators, equipment, material and days.

Phase IV – Improve

- Making improvements or optimizing processes based on measurements and analysis can ensure that defects are lowered and processes are streamlined.

Phase V – Control

- This phase ensures that any variances stand out and are corrected before they can influence a process negatively causing defects.

PROJECT EXECUTION

The project execution will be conducted using the Six Sigma tools having as expectative the evaluation, recommendation and implementation of any opportunity of quality improvement that results in a positive impact to the internal and external clients.

Define Phase

As part of the define phase a project charter was completed by the team to document a well defined project scope. A cross functional team was created involving Quality representatives, Manufacturing representatives, Planning representatives, and Engineering representatives. A SIPOC diagram was developed to initiate an

overview of suppliers, process inputs, process, process outputs, customers and customer requirements. The SIPOC diagram aided the Team on focusing in the important KPOV's to satisfy internal/external customer needs. See Figures 5 and 6.

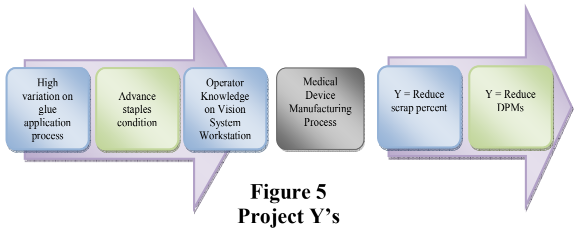

Figure 5
Project Y's

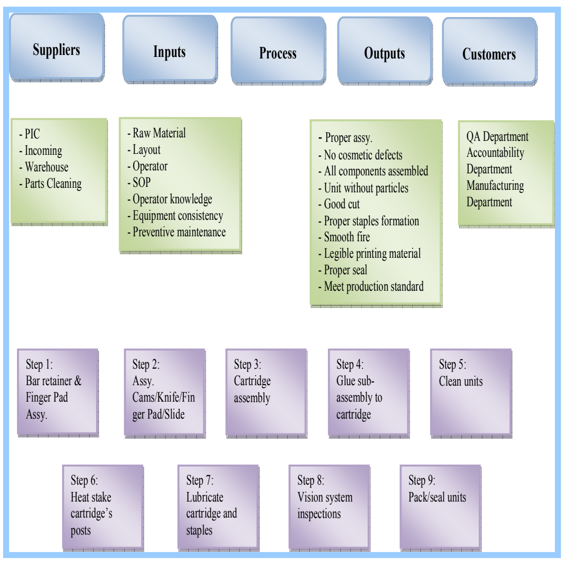

Figure 6
SIPOC Diagram

Measure phase

In the Measure phase, a detailed process map was developed, which indicated the KPIV's (77) and KPOV's (56) of process steps. A Cause and Effect (C&E) matrix was completed to evaluate the relation between the KPIV's and KPOV's with respect to customer requirements. The C&E Matrix was ranked and a Pareto Chart (Figure 7) was performed to prioritize the next step of KPIV's drill down. From the results of C&E Matrix Pareto Chart (Figure 8), five (5) KPIV's were taken to the Failure Mode and Effects Analysis (FMEA) table where the failure modes, effects and causes of the most critical key process inputs were evaluated. See Table 1. The existing controls were evaluated for these failure modes and new recommended actions and controls were taken. The new RPN #'s were recalculated to finalize PFMEA.

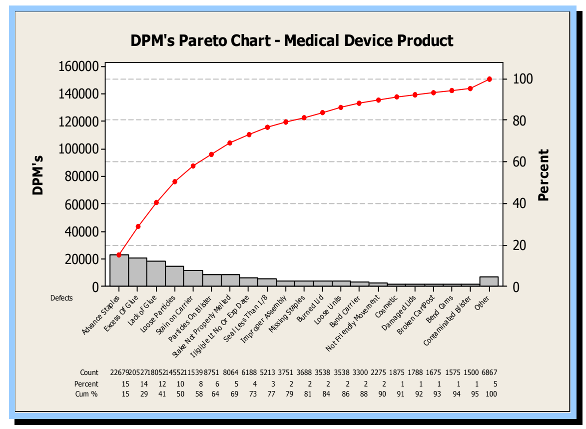

Figure 7
DPMs Pareto Chart

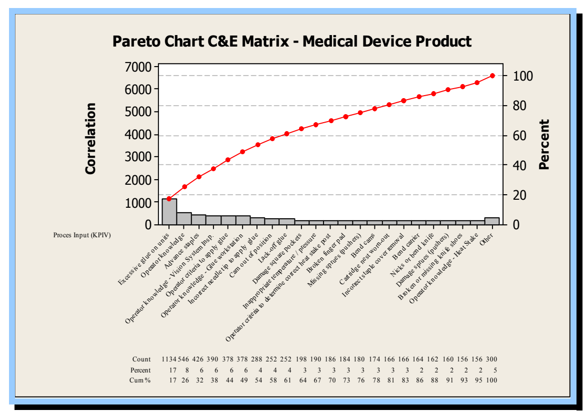

Figure 8
Pareto Chart Cause and Effect Matrix

The most critical controls were forward to the final Control Plan. These were Vision System Inspection, Glue Application Process, and the assembly process of knife/cams sub-assembly to the cartridge (see Figure 9). A Kappa Test study was performed to the Vision System Inspection process. See Tables 2 and 3 and Figure 10. The initial Kappa Test resulted in a low agreement between the inspectors and the expert (having results a K = 0.47), there was a lot of variation in the agreement Kappa Test study.

Table 1
Failure Mode and Effect Analysis

Key Process Input	Actions Recommended	Actions Taken	SEV	OCC	DET	RPN
What is the Key Process Input?	What are the actions for reducing the occurrance of the Cause, or improving detection? **Should have actions only on high RPN's or easy fixes.**	What are the completed actions taken with the recalculated RPN? **Be sure to include completion month/year**				
Advance staples	Modify the cartdridge and knife assembly fixture, placing a stop to prevent the advance staple condition	Cartdridge and knife assembly fixture was modified to prevent the advance staple condition. 01/09	9	1	3	27
Operator criteria to apply glue	Operator training. Improve the glue process using a dispenser that control the glue flow using air compressed. NP Chart	EFD Dispenser was installed on Glue Workstation and the operator were training in the use of the dispenser. 02/09 NP chart was created to monitor the excess of glue and lack of glue. 03/09	9	2	3	54
Incorrect needle tip to apply glue	Establish the appropiate needle tips to apply glue	A needle tip diameter of 0.020 inches was estabilised on the Glue Process. 02/09	9	1	1	9
Operator Knowledge	Certification program	Operator were certified on Vision System Inspection. 02/09	7	2	2	28

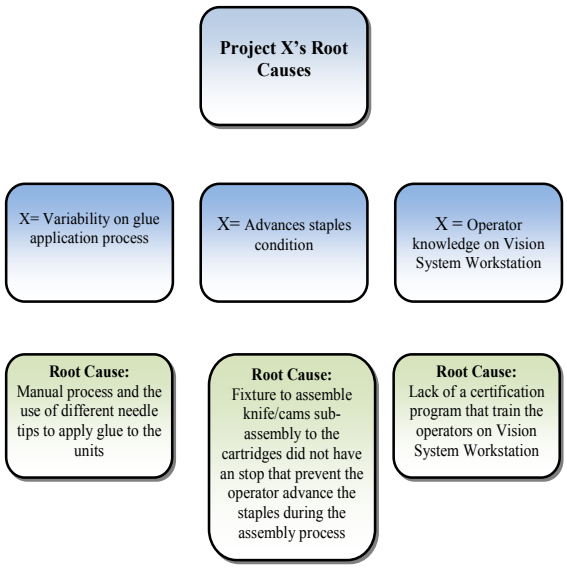

Figure 9
Project X's Root Causes

The Kappa Test was repeated after a certification program on Vision System with a significant increase of agreement between the inspectors and the expert (having a K= 0.89). The agreement results between the inspectors and the expert were acceptable. The certification program established was capable to improve considerably the agreement between the inspectors and the expert.

Analyze phase

The teams next moved towards studying if there was really a significant variation between the quantities of glue applied on the manual process vs. the EFD process.

The proper quantity of glue for each unit was established by the engineering team, applying a quantity of glue to the unit (0.136 g) which resulted in no units with excess of glue (glue on cartridges pockets, glue on cams, glue on knife and as consequence requiring an employee assign to clean the excess of glue) or units with lack of glue (resulted improper staples formation).

Table 2
Attribute Gage R&R - Before Certification Process

Fleiss' Kappa Statistics

Appraiser	Response	Kappa	SE Kappa	Z	P(vs > 0)
Opeartor 1	B	0.259259	0.182574	1.42002	0.0778
	G	0.259259	0.182574	1.42002	0.0778
Operator 2	B	0.466667	0.182574	2.55604	0.0053
	G	0.466667	0.182574	2.55604	0.0053
Operator 3	B	0.457014	0.182574	2.50317	0.0062
	G	0.457014	0.182574	2.50317	0.0062
Operator 4	B	0.466667	0.182574	2.55604	0.0053
	G	0.466667	0.182574	2.55604	0.0053
Operator 5	B	0.532814	0.182574	2.91834	0.0018
	G	0.532814	0.182574	2.91834	0.0018
Operator 6	B	0.666296	0.182574	3.64945	0.0001
	G	0.666296	0.182574	3.64945	0.0001
Operator 7	B	0.466667	0.182574	2.55604	0.0053
	G	0.466667	0.182574	2.55604	0.0053

Fleiss' Kappa Statistics

Response	Kappa	SE Kappa	Z	P(vs > 0)
B	0.473626	0.0690066	6.86349	0.0000
G	0.473626	0.0690066	6.86349	0.0000

Table 3
Agreement References

Agreement	Agreement Quality
K < 0.20	Poor
K < 0.40	Fair
K < 0.60	Moderate
K < 0.80	Good
K < 1.00	Very Good

Note: K < 0.70, requires training

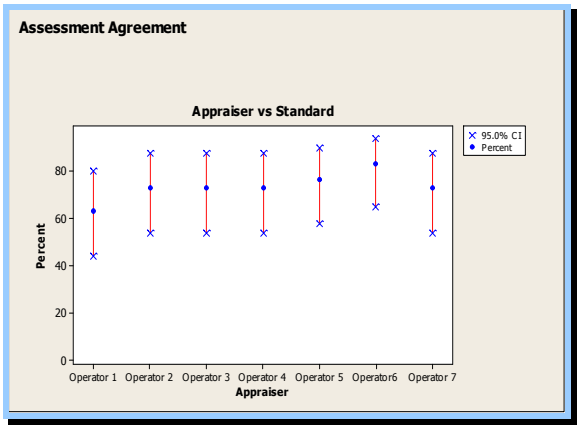

Figure10
Attribute Gage R& R Agreement Graph

During the analysis some Six Sigma Tools were used like: Histograms, Normality Test, Box plot, Regression analysis, Multi-variable test and two samples T-Test. During the analysis, a Box Plot Graphic was performed comparing Manual Glue application vs. EFD Glue Application process. A high variation of quantity of glue applied was confirmed when the units were glued using the Manual process, resulting in units with excess of glue (glue on cartridges pockets, glue on cams, glue on knife, require an employee assign to clean the excess of glue) or units with lack of glue (see Figure 11 and Table 4). A no significant variation on quantity of glue applied was reported when the units were glued using the EFD process (see Figure 12 and Table 5) .

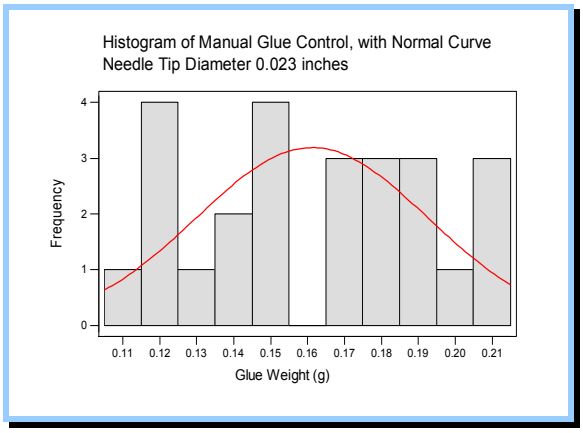

Figure 11
Histogram Manual Glue Control, Needle Tip Diameter 0.023 inches

Table 4
Histogram Data for the Manual Glue Process

Histograms Analysis:

Descriptive Statistics: Manual Control Glue, Needle Tip Diameter 0.023 in

Variable	N	Mean	Median	TrMean	StDev	SE Mean
Manual Control Glue	25	0.16124	0.16500	0.16126	0.03130	0.00626

Variable	Minimum	Maximum	Q1	Q3
Manual Control Glue	0.11200	0.21000	0.13500	0.18750

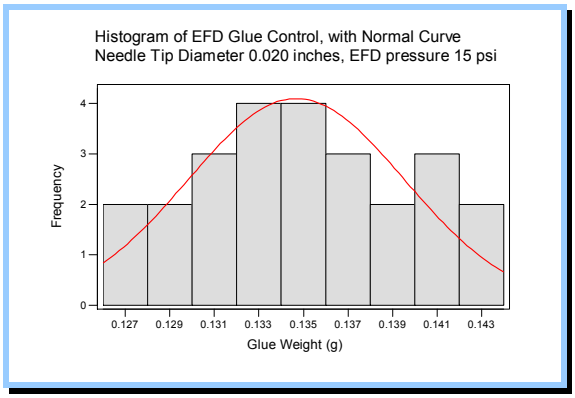

Figure 12
Histogram EFD Glue Control, Needle Tip Diameter 0.020 inches, EFD Pressure 15 psi

Table 5
Histogram Data for the EFD Glue Process

Histogram Analysis

Descriptive Statistics: EFD Glue Control – Needle Tip Diameter 0.020 inches, EFD pressure 15 psi

Variable	N	Mean	Median	TrMean	StDev	SE Mean
EFD Glue Control	25	0.13468	0.13500	0.13470	0.00487	0.00097

Variable	Minimum	Maximum	Q1	Q3
EFD Glue Control	0.12600	0.14300	0.13000	0.13900

A the two samples t-test established the following Hypothesis:

Ho: μ Manual control glue = μ EFD control glue

Ha: μ Manual control glue ≠ μ EFD control glue

The conclusion of the two samples t-test was that there is significant difference between both populations, when the operators use the Manual Glue Application vs. when the operator use EFD Glue Application. The box plot shows a high spreading data when the operators used the Manual Glue Application process. The Ho was rejected

with a p-value = 0.003 < 0.05. See Table 6 and Figure 13.

A multivariable study was performed with two different operators using a Manual glue process resulting in a significant difference between the quantities of glue applied by each operator. It is important to mention that all the data collected using the Manual or EFD process to apply glue was verified by normality and found acceptable with p-values > 0.05 (see Figures 14 and 15).

Table 6
Two Sample t-test Data

Two-Sample T-Test for Manual Glue Control vs EFD Glue Control (pressure 15 psi) Needle Tip Diameter 0.020 inches

Two-sample T for Manual - Glue Control 0.020 in vs EFD Glue Control - pressure 15

	N	Mean	StDev	SE Mean
Manual Glue Control	25	0.0802	0.0303	0.0061
EFD Glue Control	25	0.13468	0.00487	0.00097

Difference = Manual - Glue Control needle tip 0.020 in - EFD Glue Control, needle tip diameter 0.020 inches, pressure 15
Estimate for difference: -0.05444
95% CI for difference: (-0.06678, -0.04210)
T-Test of difference = 0 (vs not =): T-Value = -8.87 P-Value = 0.000 DF = 48
Both use Pooled StDev = 0.0217

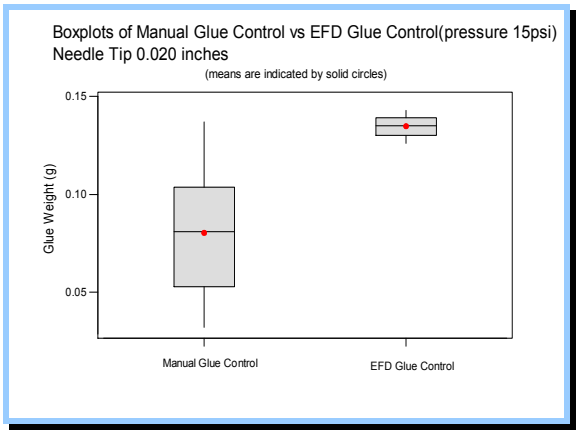

Figure 13
Boxplot Manual Glue Control vs. EFD Glue Control

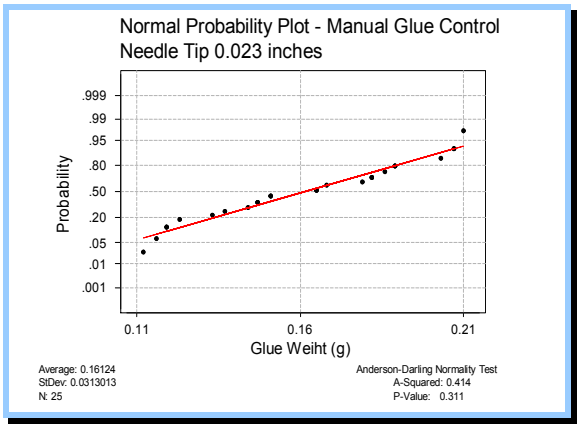

Figure 14
Normal Probability Plot for Manual Glue Control, Needle Tip 0.023 inches

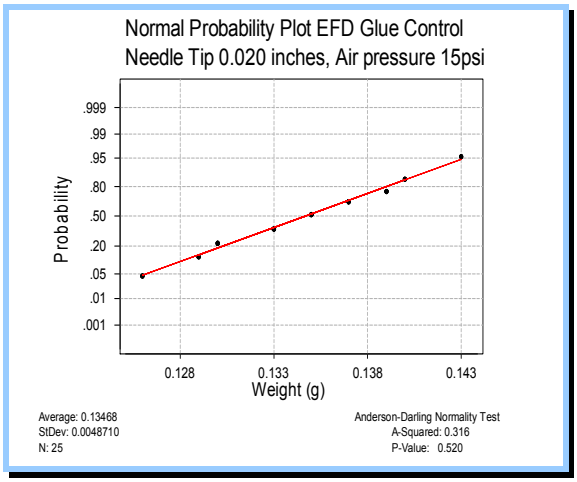

Figure 15
Normal Probability Plot EFD Glue Control, Needle Tip 0.020 inches, Pressure 15 psi

Improve Phase

In this phase, the Manual process to apply glue to the units was changed to the use of EFD process, resulting in a minimum variation of quantity of glue applied to the units and reducing the units with excess of glue or lack of glue. A new fixture was design to eliminate the advance staples condition on assembly knife/cams to cartridge workstation. See Figures 16 to 19.

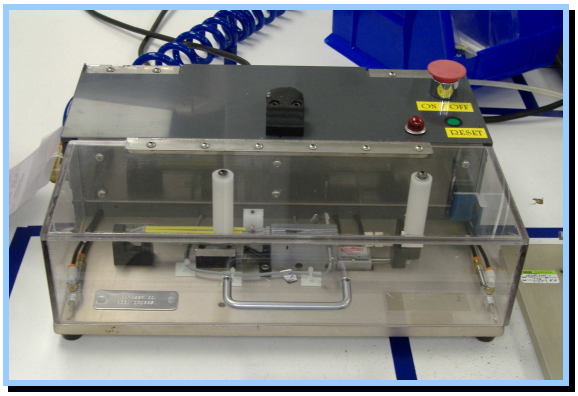

Figure 16
New Cam Adjustment Machine Implemented

Figure 17
Glue of Bottle – Before

Figure 18
Engineering Fluid Dispenser Implemented - After

Also in this phase, the Standard Operating Procedure at the Vision System workstation was modified. A certification program was implemented on the Vision System Inspection to improve the agreement between the inspectors and expert, having a K=0.89. See Table 7 and Figure 20.

Figure 19
Precision Dispensing Tips Implemented – Diameter 0.020 inches

Table 7
Attribute Gage R&R - After Certification Process

Kappa Statistics

Appraiser	Response	Kappa	SE Kappa	Z	P(vs > 0)
Operator 1	B	0.8661	0.1826	4.7437	0.000
	G	0.8661	0.1826	4.7437	0.000
Operator 2	B	0.7980	0.1826	4.3707	0.000
	G	0.7980	0.1826	4.3707	0.000
Operator 3	B	0.9327	0.1826	5.1084	0.000
	G	0.9327	0.1826	5.1084	0.000
Operator 4	B	0.9327	0.1826	5.1084	0.000
	G	0.9327	0.1826	5.1084	0.000
Operator 5	B	0.8661	0.1826	4.7437	0.000
	G	0.8661	0.1826	4.7437	0.000
Operator 6	B	0.9314	0.1826	5.1016	0.000
	G	0.9314	0.1826	5.1016	0.000
Operator 7	B	0.9314	0.1826	5.1016	0.000
	G	0.9314	0.1826	5.1016	0.000

Kappa Statistics

Response	Kappa	SE Kappa	Z	P(vs > 0)
B	0.8940	0.0690	12.9559	0.000
G	0.8940	0.0690	12.9559	0.000

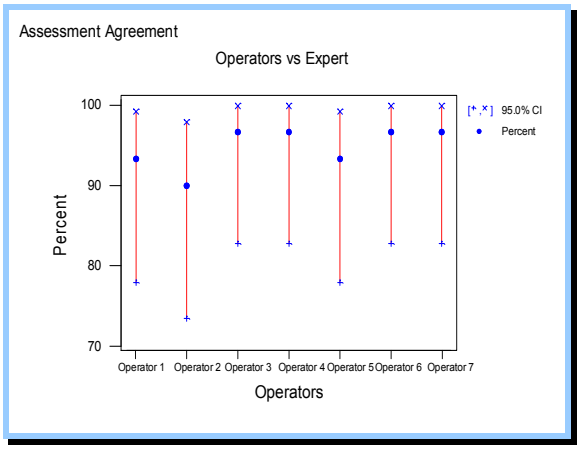

Figure 20
Attribute Gage R& R Agreement Graph

This project of Quality Improvement on a Medical Device Process resulted in $75,000 of material cost reduction and $50,000 of labor cost reduction for a total of $125,000 of savings with 50% DPM's reduction for the product. Table 8 summarizes the results of the project.

Table 8
Final Metrics Report

Name of Metric	Baseline	Goal	After Improvement	Units of Measure
DPM - Advance Staples & Improper Gluing	60,170	30,085	20,563	DPM
- Overall Process	101,864	50,932	51,813	DPM
Overall Scrap	10.19	6.0	5.18	Percent
Material & Labor Cost	9.92	9.49	9.40	$ / Unit

Control Phase

A control plan was developed to define the actions to be taken against the failure modes and most critical key process inputs controls determined in the PFMEA to maintain control of the process throughout time. The line DPM's will be monitored under the tools of the Quality program and the excess or lack of glue will be monitored with an np-Chart. One of the lesson learned is that the np-Charts enable us to take proactive action when the process becomes unstable instead of reacting to defects after they occur.

CONCLUSIONS AND RECOMMENDATIONS

This project to improve the quality for a Medical Device product was triggered by the internal customer (Manufacturing) which found that during the product assembling process a high number of units presented lack of glue or excess of glue and advance staples, affecting product line DPM's, resulting in high number of units scrapped for these conditions. These deviations from the requirements were the result of a completely manual device (plastic bottle) to apply the glue to the units and an ineffective fixture to assembly the knife/cams sub-assembly to the cartridges being used throughout the medical device manufacturing process, representing a risk to produce non-conforming units and increasing line DPM's. Also different criteria to accept or reject units on the Vision System Inspection resulted in high good units rejected or a high probability to accept non-conforming units.

With the application of the Six Sigma tools the project team has successfully improved the criteria on Vision System Inspection, glue application process, and the fixture to assembly the knife/cams sub-assembly to the cartridge.

This project resulted in $75,000 of material cost reduction and $50,000 of labor cost reduction for a total of $125,000 of savings with 50% DPM's reduction for the product.

A control plan was developed to define the actions to be taken against the failure modes and most critical key process inputs controls determined in the PFMEA to maintain control of the process throughout time.

REFERENCES

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