Process Characterization of Thermal Bond Process

Dayana M. Carrillo Velez
Master of Engineering in Manufacturing Engineering
Advisor: Rafael Nieves, PharmD.
Industrial and Systems Engineering Department
Polytechnic University of Puerto Rico

Abstract **—** Process Characterization is a required step in the commercialization of a new product. The intent of this process characterization is to ensure that the Midjoint Thermal Bond manufacturing process delivers a consistent product that complies with its design specifications and quality requirements. Product's consistency is achieved by identifying the process parameters that have direct impact in the product quality, establishing acceptance criteria and testing the operating parameters rages [1].

Statistical analysis data plays an important role identifying the Key Process Inputs (KPI) by creating a Design of experiment (DOE). A DOE analyses the interaction of the combination of process inputs to obtain the desire output. The Process Validation confirms that the KPI identified during the process characterization produces consistent product considering variations like material change and operator variability [2]. Process parameters for Midjoint Thermal Bond were defined after process characterization activities were completed. Samples built using the defined operating range parameters complied with acceptance criteria.

Key Terms — Design of Experiment (DOE), Key Process Inputs (KPI), Process characterization, Process Validation.

PROBLEM STATEMENT

A Thermal Bonding Process Validation is required as one of the deliverables of a manufacturing line transfer from a site at USA to the manufacturing site in Puerto Rico. The strategy of the transfer is to duplicate the manufacturing line and operate at the same time during volume increment and then shut down the manufacturing line at USA. This means the components, equipment, manufacturing documents, and procedures are replicated and leverage from the USA site.

When validating the the Midjoint Thermal Bond process for the Puerto Rico site, the process output did not meet the acceptance criteria using the process parameters defined in a previous validation at the USA site. This means process validation could not be leveraged and Puerto Rico site must complete a process characterization to find the optimum parameters to validate the process.

Research Description

Medical device is one of the industries that uses the most Thermal Bonding Processes in specific for Catheter Tubes. Thermal bonding for catheter tube or Thermoplastic catheter fusion is based on three types: co-joining of two faces of tubing into a bond, lap joints, and But Joint. This process consists in creating a bond by overlapping two materials, in this case, thermoplastic. For But Joint the creation of the bond involves applying simultaneously heat and pressure to both materials; then the material is cool forming a preferment bond. The heat, time and pressure parameters depend on the materials properties. A Process Characterization is required to define the process inputs that will produce a consistent product that complies with the acceptance criteria, design specification and quality requirements.

Research Objectives

The Process Characterization need to be completed to identify the KPI and Process Parameters that will meet the acceptance criteria, design specification and quality requirements for the Midjiont Thermal bond Process at the Puerto Rico manufacturing line.

Research Contribution

The contribution and scope of this Process Characterization is to identify the process parameters that will ensure product output comply with design specification and acceptance criteria. The new defined parameters will produce repeatable product and Midjoint Thermal Bond process validation completion will contribute as one of the required deliverables for the manufacturing line transfer.

RESEARCH BACKGROUND

The Thermal Bonding System is a custom standalone machine intended to complete a Catheter bonding process between the Exhaust Tube and the Window Tube. The Exhaust tube is loaded onto a process mandrel and butted up with the Window tube. A Heat shrink tubing is loaded over tubing joint and then loaded into the Thermal Bonding Platform, Figure 1 shows the exhaust tube assembly before thermal bond process. Once at the equipment platform, the heat shrink and components are aligned using a crosshair generator in a monitor. Upon initiation of the machine cycle, heated dies close over the assembly to reflow the components. After cycle completion, the assembly is removed from the machine and the heat shrink and mandrel are removed from the part. The Thermal Bonding System utilizes electricity and compressed air. All settings: Temperature, Die Head Pressure, Grip Pressure and Dwell Time are controlled using dials and switches located on the front panel of the equipment. This equipment utilizes timers and relay logic and uses no software [3].

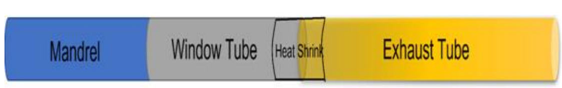

Figure 1
Exhaust Tube Assembly before Midshaft Thermal Bond Process

Process Inputs

The scope of Process Characterization Strategy is to identify process parameters that impact on the product quality and yield by:

- Recognizing the interactions between the process parameters and the design specification.
- Identifying the manufacturing operating ranges and acceptance criteria.
- Confirming that the process builds a product with reproducible yields that meets the design specification.
- Finding potential manufacturing deviations by using the established control strategy and knowledge about the effect of process inputs on product quality.

Table 1 provides a summary of the sources of input variation and its effect on process output and the control method for the Midjoint thermal bond process.

Table 1
Process Inputs

Potential Source of Variation	Effect on Process Output	Control Method (if applicable)
Dwell Time	• High dwell time may cause bubbles, necking and low Tensile Strength. • Low dwell time may cause failure meeting Bond outside diameter (OD), low Tensile Strength and visual defects.	-Thermal Bond Manufacturing Procedure
Temperature	• High temperature may cause bubbles over 0.4mm^2, or more than one bubble, necking, Strength Failure, and visual defects that could lead to nonconforming parts. • Low Temperature may cause, Bond OD max failure, Midjoint Bond Tensile Strength Failure and Visual defects as cold flow lines, gap in the bond.	-Thermal Bonding Set-Up procedure. -Thermal Bond Manufacturing Procedure

Grip Pressure	• High pressure no effect. • Low pressure may cause, Bond OD max failure, Midjoint Bond Tensile Strength Failure, and Visual defects as cold flow lines, gap in the bond.	-Thermal Bonding Set-Up procedure. -Thermal Bond Manufacturing Procedure
Die Head Pressure	• High pressure no effect. • Low pressure may cause, Bond OD max failure, Midjoint Bond Tensile Strength Failure, and Visual defects as cold flow lines, gap in the bond.	-Thermal Bonding Set-Up procedure. -Thermal Bond Manufacturing Procedure
Mandrel	• Low size Internal diameter (ID) out of specification incorrect Bonding Mandrel size. • High size Bond OD max cause by an incorrect Bonding Mandrel size	-6F Bonding Mandrel print document -Thermal Bond manufacturing procedure and Manufacturing Executive System (MES)
Overlapping	• Bump in tube Bond OD max out of specification	-Thermal Bonding Set-Up procedure. -Thermal Bond Manufacturing Procedure
Step Mandrel not flush with the end of 6F tube	• Indent tubing	-Thermal Bonding Set-Up procedure. -Thermal Bond Manufacturing Procedure
Cooling Duration Timer	No effect	-Thermal Bonding Set-Up procedure. -Thermal Bond Manufacturing Procedure
Axial Compress Delay Timer	No effect	-Thermal Bonding Set-Up procedure. -Thermal Bond Manufacturing Procedure
Material	• Incorrect heat shrink • Damage tubing • Dirty tubing	-Thermal Bonding Set-Up procedure. -Thermal Bond Manufacturing Procedure
Set Up	Incorrect setup	-Thermal Bonding Set-Up procedure. -Thermal Bond Manufacturing Procedure
Air Pressure	• If pressure is too high, it could damage the Exh. Tube W/Windows that could lead to scrap the unit as per Midjoint Thermal Bond manufacturing procedure. • If the pressure is too low, it could lead to a possible tensile pull strength failure. Midjoint Thermal Bond tensile pull strength shall be greater than or equal to 3.38 lbs.	-Thermal Bonding Set-Up procedure. -Thermal Bond Manufacturing Procedure
	• Pressure gauge incorrect pressure reading, it could lead to a possible tensile pull strength failure or damage the EXH. Tube W/Windows and Heat Shrink causing flared edges that could lead to scrap the unit.	- Annual pressure gauge calibration.
Operator	• 6F Tube not fully inserted or over inserted into the EXH. Tube W/Windows. It could damage the assembly making a gap, indent or protrusion in the tubing as per manufacturing procedure.	-Thermal Bonding Set-Up procedure. -Thermal Bond Manufacturing Procedure
	• Exhaust tube Assy pull strength shall be greater than or equal to 03.38 lbs as per product document.	

Process Outputs

The process output or requirements that demonstrate the product meet the expected criteria are listed in Table 2. For this thermal bond, tensile strength, bond outer diameter, and visual inspection are evaluated to determine the process is performed as required.

Table 2
Process Output

Midjoint Thermal Bond	
Process Output	Source Document
The minimum Midjoint pull strength $\geq$ 3.38 lbs	Design Print of Exhaust Tube Assy
Bond OD .081 +0.000/-0.005 inches	

Acceptance Criteria	Source Document
• No bubbles greater than 0.4 mm2 at the bonding area • No Foreign material greater than 3 mm² present at the bonding area of the tube. • No Bump present in bonding area of tube. • No Visible indent present at the bonding area of the tube. • No visible cold flow line in bonding area of the tube. • No visible gap presents in bonding area.	Visual Standard Document

Equipment

Table 3 listed the equipment and tool required to perform the thermal bond manufacturing process and testing.

Table 3
Process Equipment

Equipment	Model	Qualification Report/Calibration
Instron Force Tester	5543	Qualification
Bond Size Gage	OD 0.081 inches	Calibration
Axial Compression Thermal Bonder	420-B	Qualification

The Axial Compression Thermal Die Bonder has a dual Pneumatic tubing grip, centerline adjustment, adjustable compression, and variable timed cooling. This systema for RF die bonding has seven parameter operations and is easy to set-up and use and simplifies system calibration and process validation. This system provides fast and highly repeatable bonds. Adjustable clamp pressure varies compression force on joint for applications such as butt welds. The facility requirements for this equipment are [3]:

- 110/120 v
- 50/60 hz 2-3 amps (220 watts)
- 80-100 psi, clean dry compressed air

Material

From the material standpoint, only two components are needed to complete the thermal bond manufacturing process, are listed below. In terms of supplies, a shrink is used to complete the process in each assembly.

- Exhaust tube - Pebax 7233 Med Clear
- Window tube – Pebax 6333

METHODOLOGY

The purpose of this test was to identify possible factors and determine whether they have a significant impact on the Midjoint Thermal Bond Pull Strength of the Exhaust Tube Assy. Samples of Exhaust Tube Assy were prepared and tested in the Clean Room using the Thermal Bonding System under normal operating conditions per Controlled Manufacturing Areas General Requirements. Table 4 contains the Process parameters of the USA manufacturing site that could not be leveraged because the P.R. process output did not meet the acceptance criteria.

Table 4
USA manufacturing Site Thermal Bond Normal Operating Parameters

Parameter	Low	Nominal	High
Die Head Pressure	10 psi	15 psi	20 psi
Die Temp	420°F	425°F	430°F
Grip Pressure	5 psi	10 psi	15 psi
Dwell Time	41 s	45 s	49 s

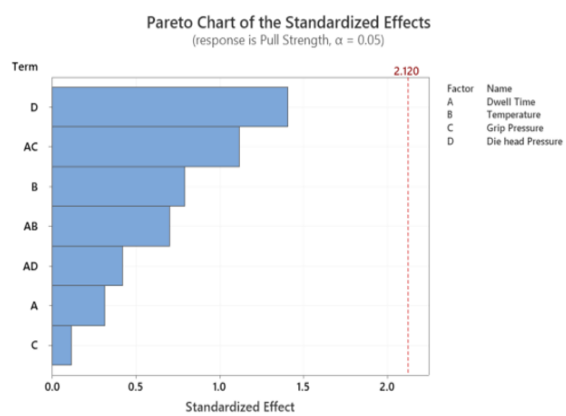

Figure 2
Pareto Chart of Standardized Effects

A fourth-factor resolution full factorial DOE with one center point was chosen for a total of 25 runs. The fourth factors used Dwell Time, Temperature, Die Head Pressure and Grip Pressure parameters. A resolution full factorial was chosen to obtain the maximum resolution within the factors. Minitab v.19 was used to analyze results on the Midjoint Thermal Bond Process based on DOE input combinations. A full factorial Pareto Chart of the Effects for Midjoint Pull Test was generated in order to evaluate the effects of these potential key sources of variability. An alpha $\alpha = 0.05$ was maintained for the analysis (See Figure 2).

Nevertheless, parameters of Table 4 were used as a reference for P.R. site DOE. Table 5 contains the process settings that were considered to define the normal operating range.

Table 5
Evaluated Setting for Normal Operating range for P.R Site

Parameter/ Setting	Value
Dwell Time	45 sec - 65 sec
Temperature	420°F - 430°F
Grip Pressure	5 psi - 30 psi
Die Pressure	5 psi - 30 psi

Based on the sampling size used for the test, the Pareto Chart indicates a trend of Factor D (Die Head Pressure) and Factor AC (Dwell Time & Grip Pressure) as potential statistically significant factors [4]. In addition, the Main Effect Plot analysis was performed to see the relationship between factors and pull strength. Was observed that change in Die Pressure has more impact in the Pull Test results than Dwell Time and Temperature factors (See Figure 3).

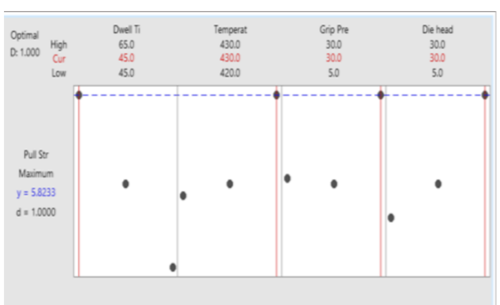

Figure 3
Main Effect Plot for Exhaust Tube Assy

Based on the sampling size used for the test, the Pareto Chart indicates a trend of Factor D (Die Head Pressure) and Factor AC (Dwell Time & Grip Pressure) as potential statistically significant factors. In addition, the Main Effect Plot analysis was performed to see the relationship between factors and pull strength. Was observed that change in Die Pressure has more impact in the Pull Test results than Dwell Time and Temperature factors (See Figure 3).

Response Optimizer Chart was performed to identify the potential combination of factors settings that jointly optimize the Pull Strength. See Figure 4.

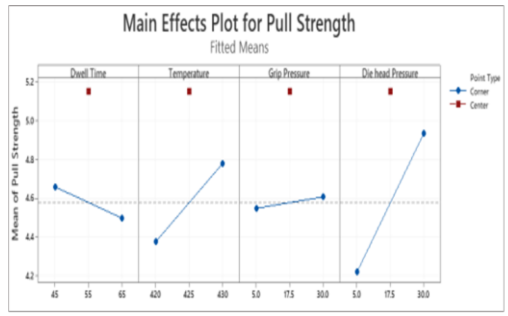

Figure 4
Optimizer Chart

Based on the Optimizer Chart Results, the Process Characterization settings for the Exhaust Tube Assembly as follow:

Once the process parameters were statistically defined, fifteen (15) samples were manufactured for each process condition (NOR Low, Nominal and NOR High) for a total of forty-five (45) samples. Units were built following the normal production according to the Midjoint Thermal Bond manufacturing instruction using time, temperature and pressure parameters as listed in Table 4. Samples were visually inspected, and the Exhaust Tube Assy diameter was verified using the Go No Go Gage. The samples were then submitted to tensile pull strength following test method Mid-Joint Pull and analyzed for data distribution and capability.

Table 6
Final Operating Parameters for Exhaust Tube Assembly

Parameter/ Setting	Low	Nominal	High
Dwell Time (seconds)	50	53	55
Temperature (Fahrenheit)	420	425	430
Grip Pressure (psi)	15	22.5	30
Die Pressure (psi)	15	22.5	30

Results and Discussion

Exhaust Tube Assy was built using NOR Low parameter settings according to Table 7. All samples were inspected following the visual acceptance criteria and pull strength specification. As result the data complies with normality test, $p>0.05$. Process Capability Sixpack analysis was performed resulting with a Ppk =3.45, greater than the acceptable Ppk $\geq$0.69 for a sample size of 15 for a variable data with 95/90 of confidence / reliability (Figure 5).

Table 7
Parameters Range for Process Characterization

Parameter (Factors)	Value Range
Dwell Time	50 sec - 60 sec
Temperature	420°F - 430°F
Grip Pressure	15 psi - 30 psi
Die Pressure	15 psi - 30 psi

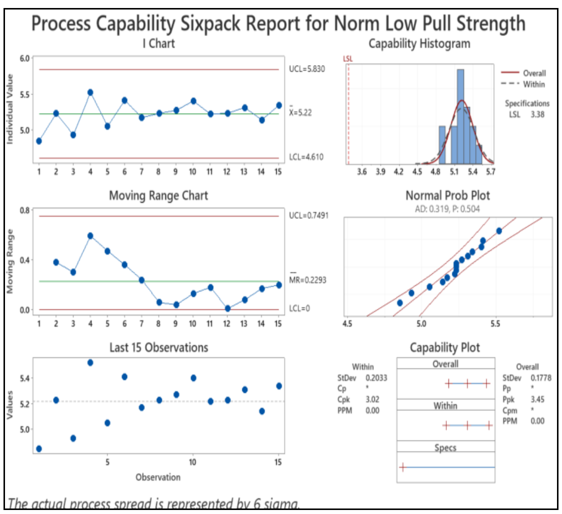

Figure 5
Process Capability Report for Norm Low Parameter Settings

Exhaust Tube Assy was built using Nominal parameter settings according to Table 7. All samples were inspected following the visual acceptance criteria and pull strength specification. As result the data complies with normality test, $p>0.05$. Process Capability Sixpack analysis was performed resulting with a Ppk =1.98, greater than the acceptable Ppk $\geq$0.69 for a sample size of 15 for a variable data with 95/90 of confidence / reliability (Figures 6 and 7).

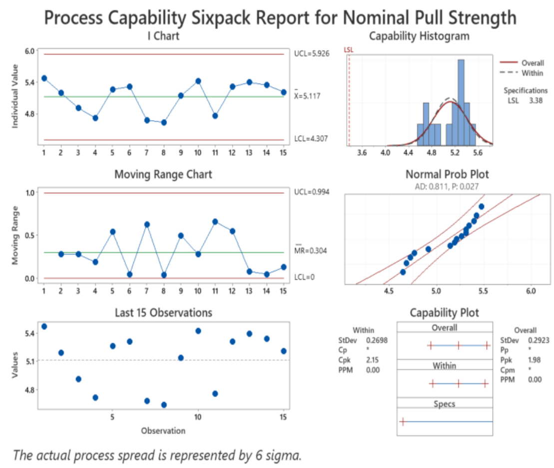

Figure 6
Normality Screening Assessment Nominal Parameter Settings

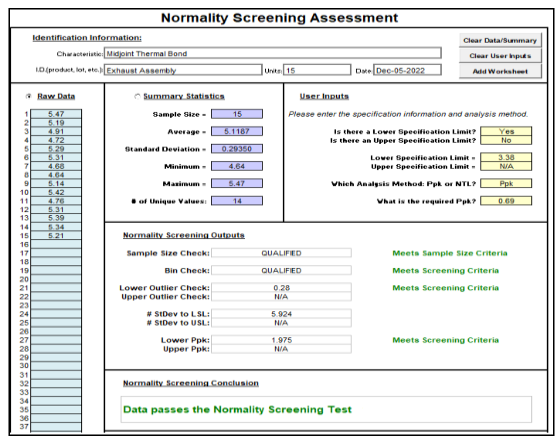

Figure 7
Normality Screening Assessment Nominal Parameter Settings

Exhaust Tube Assy were built using Nor high parameter settings according to Table 7. All samples were inspected following the visual acceptance criteria and pull strength specification. As result the data complies with normality test, $p>0.05$. Process Capability Sixpack analysis was performed resulting with a Ppk =1.44, greater than the acceptable Ppk $\geq$0.69 for a sample size of 15 for a variable data with 95/90 of confidence / reliability (Figure 8).

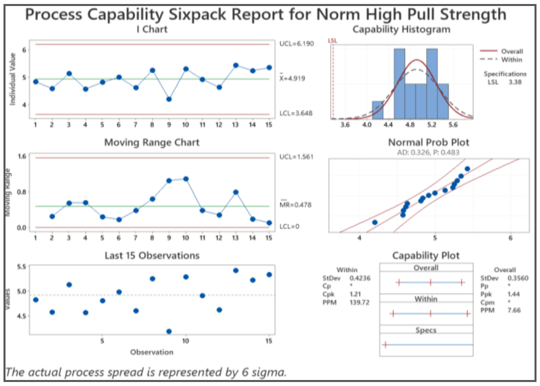

Figure 8

Normality Screening Assessment High Parameter Settings

CONCLUSION

The scope of this report was to characterize Midjoint Thermal Bond Process to define process conditions and control limits for Key Process Inputs (KPI). All Process Characterization testing has been executed and NOR Low, Nominal and NOR High Operating Range for Midjoint Thermal Bond Process has been defined. Operating ranges for each parameter are the following: Dwell Time 50 – 60 seconds, Temperature 420°F - 430°F, Grips pressure 15 psi - 30 psi and Die head pressure 15 psi - 30 psi. All samples complied with specifications as per the manufacturing instruction and met the minimum Pull Strength specification (3.38 lbs.) min specified in the product drawing. Process Capability Sixpack analysis for samples built with NOR Low, Nominal and NOR High Operating Range resulted with a Ppk greater than the acceptable Ppk $\geq$0.69 for a sample size of 15 for a variable data with 95/90 of confidence/ reliability.

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