Catheter bonding process improvements with high-intensity ultraviolet curing systems

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Abstract

Ultraviolet (UV) curing is a common process used in medical devices manufacturing for bonding operations. Light-curable adhesives provide rapid cure, great adhesion, and good chemical resistance for sterilization processes. This project studies the effect of the implementation of a new UV curing technology for manifold catheters manufacturing. The upgrade consists of moving from the current mercury light bulb UV to an LED bulb. Benefits from improvements include energy savings, improved process performance, and reduction of maintenance activities. Process performance is evaluated by its capability of meeting the tensile force design spec of 3.38lbf. Key Process Inputs (KPI) that affect the tensile strength output are UV Intensity and Process Cure Time. A Design of Experiments explored the lower and upper limits of adhesive curing time and intensity parameters, and their impact on tensile values.

Introduction

This project will study the effect of the implementation of a new ultraviolet (UV) curing technology for epoxy adhesive curing of catheters manufacturing. The current curing process uses American Ultraviolet Lesco MKIII SuperSpot. This equipment is determined to be upgraded to the Dymax MX-150 Spot Cure system. The fundamental difference between the two systems are the source of UV energy. The Lesco uses a 100W Mercury bulb to produce a wide spectrum of UV light (320-460nm), while the Dymax system uses an LED bulb that produces a narrower band of UV light (~365nm). Additionally, the Dymax system has an integrated user interface that allows for recipe control and will make the process easier to operate.

Background

Sealants and adhesives are used in many industries, their main purpose is to bond and or seal joints of materials; these can also provide vibration damping and corrosion protection. The need to reduce cure times and energy consumption opened the door to new technologies using the light electromagnetic spectrum sources to initiate and accelerate adhesive cure. Recent research studied the differences between LED lamp and mercury lamps for UV curing. The results showed that a homogeneous light distribution allows a higher photonic efficiency. LED lamps, provide an improvement to light homogeneity and energy efficiency, creating higher curing rates. The characteristics of the material to be bonded can affect cure, at least one of the components to be bonded must be translucent within the adhesive's absorption range. UV bonding process for this study is comprised of a UV light source, cure box, nitrogen purge box, and light-curable acrylic Loctite adhesive. Compress nitrogen, removes oxygen from the area which acts as an inhibitor for UV curing. Reducing the oxygen level to the cure area, increases the curing performance.

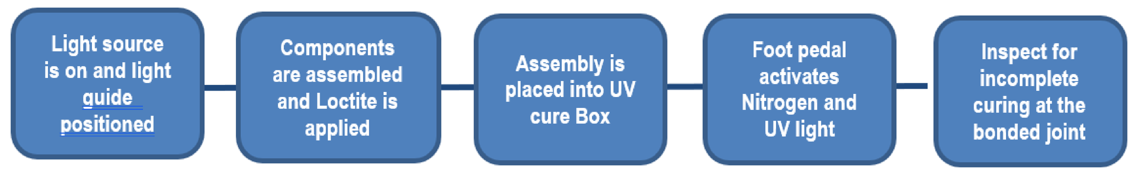

Figure 1: UV Bonding Process

Problem

This test study's purpose is to explore the lower limits and identifying potential failure points and minimum values required to meet our tensile outputs. Test results that characterize the UV Bonding process are needed to define optimum process conditions and control limits for critical process inputs. The impact on tensile strength will be considered and the critical process inputs determined. By updating the UV technology for the bonding cure, it is expected to improve the manifold bond process and equipment, including the reduction of curing defects, process cycle time, and maintenance costs.

Methodology

This test study challenges the lower limits of our time and intensity parameters and their impact on tensile values. The effectiveness of the cure will be measured based on the ability to meet the design spec of 3.38lbf for the bonded joint tensile strength. The test will be conducted in the same clean environment that current manufacturing for catheter assemblies occurs. The study will feature three (3) different catheter manifold parts, purple, grey and clear. For which the purple manifold, will simulate a worst-case scenario during challenge testing since it can filter up to 85% of UV Light source. A Full Factorial DOE for the Feasibility Test with two factors, UV Intensity with five (5) levels and Product Color with three (3) levels against the tensile strength output of minimum 3.38lbf. DOE for UV intensity Feasibility Test for will be run three (3) times for a total of 45 samples, with n=15 for each manifold color. A second run of n=30 samples for the purple manifold will evaluate curing time variation against the worst-case material. Edge of Failure test will be run one (1) time for a total of 90 samples, with n=30 for each manifold color. The two experiments described on Table 1, will define Normal Operating Conditions (NOC) and Edge of Failure (EOF) for the manifold catheters bonding process.

Table 1: Experiments Objective and Test Parameters

Test Name	Test Objective/Purpose	Experiment Parameters: UV Intensity (W/cm2)	UV Intensity Value (%)	Cure Time (sec)	Adhesive Amount (cc)
Feasibility Testing	Verify that at the lower limit for variable UV intensity, the units pass attribute testing and are statistically capable for variable testing.	1.0	10, 30, 50, 70, 90	8	30
Edge of Failure	Test parts around the perceived low end and upper limits of the process range to give insight to the tensile strength at lower and higher UV doses.	Low 1.0 Upper 10	Low 8 Upper 80	Low 10 Upper 30	30

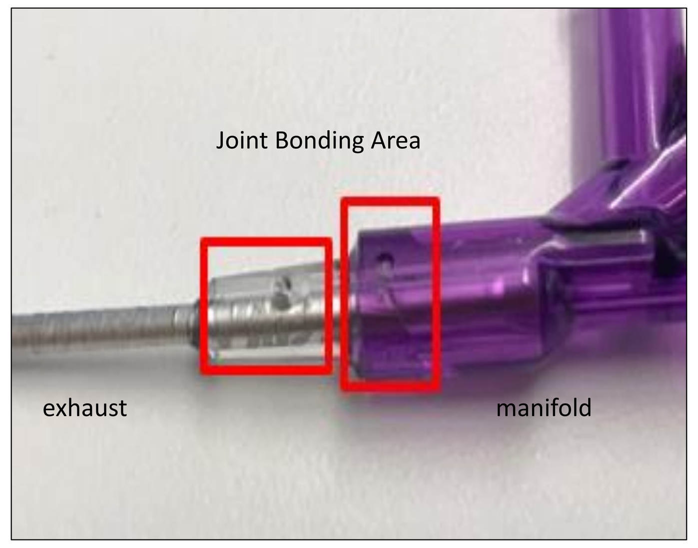

Figure 2: Manifold to Exhaust joint bonded assembly example

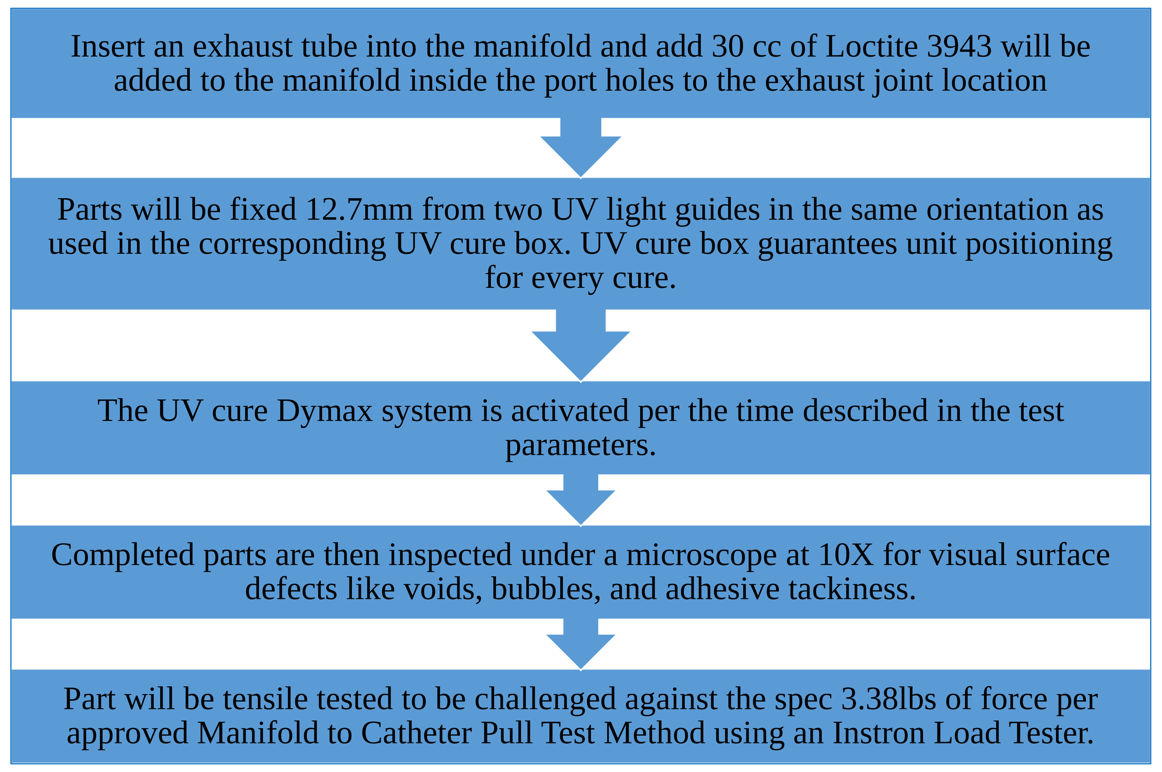

Figure 3: Sample preparation and evaluation process

Results and Discussion

All test parts evaluated for the completed experiments, met or exceeded the required tensile strength output of >3.38 lbs. All samples were inspected for surface defects and no signs of voids, bubbles, or uncured adhesive was found. By analyzing the DOE results P-value for all factors are 0.00; this means that there is strong of significant association between the response variable and the term. This confirms that the material colorant affects the process output due to the UV filtering capacity.

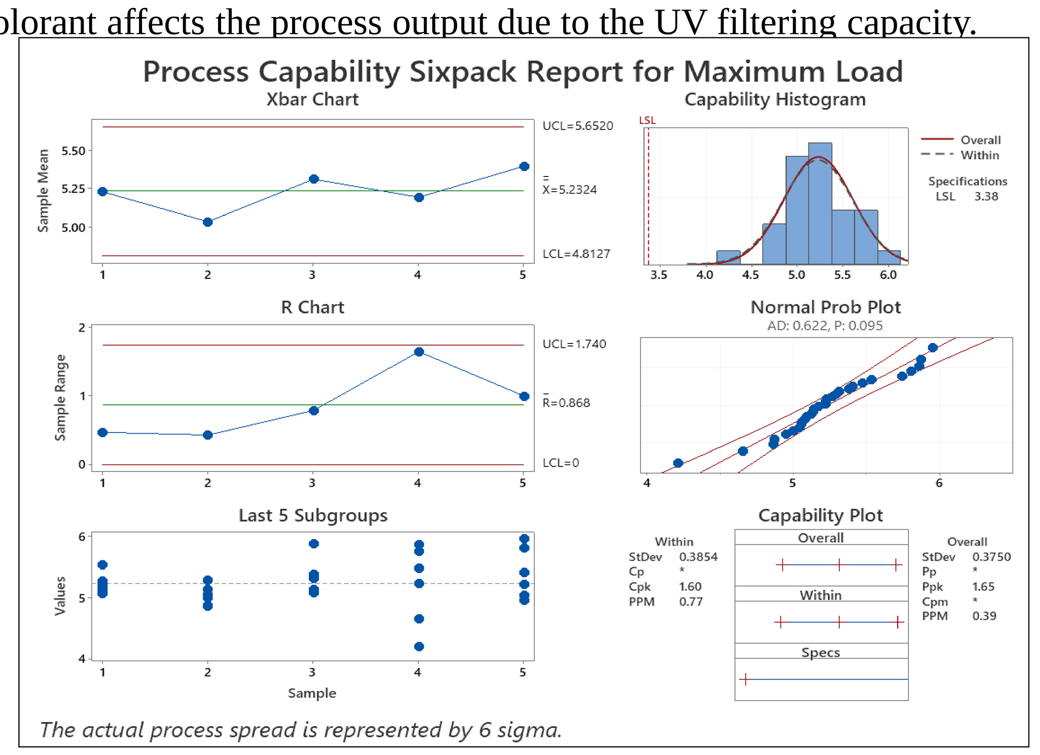

Figure 3: Feasibility Test Process Capability Results for Purple Manifold

Table 2: Edge of Failure Test Results Summary

Manifold-Edge	Tensile Output Mean (lbf)	Distribution	P-Value	Ppk
Purple-Low	4.031	Normal	0.681	1.49
Purple-High	5.05	Normal	0.528	1.93
Grey-Low	5.18	Normal	0.272	3.28
Grey-High	10.22	Normal	0.232	1.85
Clear-Low	23.52	Normal	0.969	1.41
Clear-High	33.79	Normal	0.357	1.46

When analyzing the failure modes, it is expected to see an adhesive failure, this means the bonded joint area broke at the documented tensile force. However, some tensile failures occurred due to the exhaust tube breakage instead of the bonded joint. Failures due to a break in the exhaust tube, occurs prior to adhesive failure, which means that the limiting factor in this build was not the quality of adhesive curing, but rather the tensile strength of the proximal exhaust tube. These experiments were successful in showing that even under worst case conditions, adhesive curing is still capable at meeting required tensile values.

Spec	Current Equipment: Lesco Super Spot MKIII*	New Equipment: Dymax Blue Wave MX-150**	Upgrade Benefit
Picture			Digital Touch Screen Improved user interface Curing programs can be easily entered, stored, and recalled when needed
Dimensions	8.5" x 11" x 13.5"	5.14" x 7.19" x 7.35"	Smaller footprint, allows for better workstation space utilization
Lamp Bulb Type	100W DC Mercury Vapor	LED Bulb	More energy efficient
Lamp Bulb Life	2,000 hrs	>5,000 hrs	Better equipment reliability Less maintenance cost Longer useful life
UV Output	20 W/cm2	24 W/cm2	Higher intensity improves adhesive curing
Warm Up Time	15-30 min	No warmup needed	Less setup/changeover time Improved process cycle time
Warranty	1 Year	1 Year	N/A
Equipment Cost	$ 6, 250	$ 6, 850	Higher inversion during equipment acquisition is offset by energy, cycle time, and maintenance costs savings
Light Bulb Replacement Cost	$ 550	$1, 304	

Figure 5: Equipment comparison and upgrade benefits

Conclusions

Is the process output complaint with the required specification of >3.38lbf? Is the process capable of absorbing process variation in curing time, UV intensity, material changes, and still meet the required tensile output? The answer to these questions is yes. The Feasibility and Edge of Failure testing proved that the new equipment is capable of successfully curing the adhesive while meeting the tensile and surface defects requirements. The Key Process Inputs (KPIs) were determined to be UV Intensity and Curing time. The use of nitrogen in this case was proved to have no impact into the adhesive curing, so this variable could be an item to evaluate in the future. Elimination of the nitrogen use can potentially provide big cost savings to the catheters manufacturing process. This research was successful in characterizing and establishing the new process parameters for the Dymax LED UV cure system. The research contributions for improved equipment reliability, process performance is evident with the equipment upgrade that the new Dymax Blue Wave offers in comparison with the current manufacturing process. One of the major items in terms of cost and time is the equipment maintenance activities, this new equipment provides longer UV lamp life which directly impact the labor and costs incurred in maintenance work orders.

Future Work

The manifold color variant was a variable identified during this process that proved to impact tensile output due to its ability to filter UV light. However, manifold design is a variable that cannot be changed of adjusted for the current product design and process, nor is within the scope of this study. The purple manifold product, D-120, is the catheter with the lowest tensile strength output. A potential future research can involve identifying a new manifold material or colorant that still provides the cosmetic design needs (purple color) but that has a lower UV filter capacity. In general, polycarbonate materials like the manifold in this study affect the curing performance, if the colorant variable can be addressed process capability can be improved and it can open the process to be applied in other catheter product families.

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