Studying and Troubleshooting Lubricity Test on Pressure Guidewire Proximal and Distal Coatings

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Abstract

Coatings of guidewires used in medical device manufacturing industry are one of the most important aspects. It defines its efficiency to penetrate through tightest of canals and curves. Guidewires are put through controlled environment to accelerate its age and tested for its mechanical features. Pressure Guidewire failed the lubricity testing after being tested by multiple operators and at alternate sites. A cause-and-effect diagram shows all potential causes of test failure. The human factor involved in the test failure was investigated through multiple Gage R&R and training records. Calibration error with the lubricity tester DL1000 was identified and solved through preventive maintenance work order. The failed samples were examined under Scanning Electron Microscope and detailed images showed coating wearing off from T=2years samples. A two-factor design of experiment factorial was conducted to see the effects of factors on distal and proximal sections of the wire. The actual setting of Corona distance 5mm and Dip speed 60mm/min seem to affect the coating of proximal section during aging process. A new optimize setting of Corona distance 2mm and Dip speed of 30mm/min proved to provide better coating that can sustain the wire over the 2 years. Similarly, for distal section of Pressure Guidewire, UV intensity of 6.0 and Corona time of 30seconds showed better results as compared to original setting. A confirmation study was conducted to prove the effects of new changes implementation and process capability showed that the results were under control.

Keywords
Guidewire, Gage R&R, Lubricity, Design of Experiments, and Coatings.

1. Introduction
The purpose of this paper is to investigate the coating wear, identify the optimal treatment settings, implement the changes, and verify the resulting changes through Design of Experiments (DOE) analysis. This study can help optimizing and improving the sustainability of guidewire coating for a longer time. During aging study, a certain lot and batch of Pressure Guidewire samples failed the lubricity and durability testing. The results showed that the material was out of specification for both, proximal and distal sections of Pressure Guidewire. This study provided detailed analysis on different factors that contributed to the lubricity testing failure. The measurement system, human factor, and machine, all contributed to testing failure to a certain extent and the variance was calculated using DOE. Coating of Pressure Guidewire was the leading factor, as proved both through DOE and SEM images. This study helped essentially in fixing the coatings processes of guidewire and make the product more sustainable over the time.

1.1 Objectives
The primary objective of this research is to identify the optimal settings for corona treatment of guidewire coating. The corona distance, corona dip speed, UV intensity and corona time are primary factors influencing the coating process of proximal and distal sides of guidewire. The data will be justified based on the interaction of factors given in the Table 1 below:

Table 1. Hypotheses of different interaction of factors

Proximal Null Hypotheses

Corona Distance	Mean Lubricity at Corona Distance 2 = Mean Lubricity at Corona Distance 5
Dip Speed	Mean Lubricity at Dip speed 30 = Mean Lubricity at Dip Speed 60
Corona Distance * Dip Speed	Mean Lubricity at Corona Distance 2 and Dip Speed 30 = Mean Lubricity at Corona 2 and Dip Speed 60 Mean Lubricity at Corona Distance 5 and Dip Speed 30 = Mean Lubricity at Corona 5 and Dip Speed 60 Mean Lubricity at Corona Distance 2 and Dip Speed 30 = Mean Lubricity at Corona 5 and Dip Speed 30 Mean Lubricity at Corona Distance 2 and Dip Speed 60 = Mean Lubricity at Corona 5 and Dip Speed 60
Proximal Alternate Hypotheses	
Corona Distance	Mean Lubricity at Corona Distance 2 ≠ Mean Lubricity at Corona Distance 5
Dip Speed	Mean Lubricity at Dip speed 30 ≠ Mean Lubricity at Dip Speed 60
Corona Distance * Dip Speed	Mean Lubricity at Corona Distance 2 and Dip Speed 30 ≠ Mean Lubricity at Corona 2 and Dip Speed 60 Mean Lubricity at Corona Distance 5 and Dip Speed 30 ≠ Mean Lubricity at Corona 5 and Dip Speed 60 Mean Lubricity at Corona Distance 2 and Dip Speed 30 ≠ Mean Lubricity at Corona 5 and Dip Speed 30 Mean Lubricity at Corona Distance 2 and Dip Speed 60 ≠ Mean Lubricity at Corona 5 and Dip Speed 60
Distal Null Hypotheses	
UV Intensity	Mean Lubricity at UV Intensity 2 = Mean Lubricity at UV Intensity 6
Corona Time	Mean Lubricity at Corona Time 30= Mean Lubricity at Corona Time 10
UV Intensity * Corona Time	Mean Lubricity at UV 2 and Corona Time 30 = Mean Lubricity at UV 2 and Corona Time 10 Mean Lubricity at UV 6 and Corona Time 30 = Mean Lubricity at UV 6 and Corona Time 10 Mean Lubricity at UV 2 and Corona Time 30 = Mean Lubricity at UV 6 and Corona Time 30 Mean Lubricity at UV 2 and Corona Time 10 = Mean Lubricity at UV 6 and Corona Time 10
Distal Alternate Hypotheses	
UV Intensity	Mean Lubricity at UV Intensity 4 ≠ Mean Lubricity at UV Intensity 6
Corona Time	Mean Lubricity at Corona Time 30 ≠ Mean Lubricity at Corona Time 10
Corona Distance * Dip Speed	Mean Lubricity at UV 2 and Corona Time 30 ≠ Mean Lubricity at UV 2 and Corona Time 10 Mean Lubricity at UV 6 and Corona Time 30 ≠ Mean Lubricity at UV 6 and Corona Time 10 Mean Lubricity at UV 2 and Corona Time 30 ≠ Mean Lubricity at UV 6 and Corona Time 30 Mean Lubricity at UV 2 and Corona Time 10 ≠ Mean Lubricity at UV 6 and Corona Time 10

2. Literature Review

Lubricity test is a process used to measure the ability of a substance to reduce friction between two surfaces in relative motion (Jamison & Vos, 2020). In terms of wire, lubricity testing includes evaluating the effectiveness or ability of wire coating material to reduce friction between wire and surrounding which in our case would be arteries and veins. With endovascular catheters, the major goal of commercially available hydrophilic coatings is to increase lubricity and maintain low and steady friction for the relatively short distance that the catheter slides across the vessel wall during the procedure (Niemczyk et al.2015). For catheters, one of the primary attribute is the biocompatibility with lubricity (Kazmierska, Szwast, & Ciach, 2008). Lubricity friction testing is a very important aspect of guidewire development in the medical device manufacturing because it involves patient's safety and wire's ability to penetrate through tightest of canals which could potentially include inner blockage. Lubricity is important when it comes to tensile stress on the wire because this may impact the durability of wire (Atienza et al. 2012). Therefore, a good amount of time is spent on research and development of wire coatings and its functional properties. (Forman et al., 2021) tested lubricity of popular guidewires and investigated how lubricity features behave towards vascular damage.

Polytetrafluoroethylene (PTFE) is a highly chemical resistance, synthetic fluoropolymer, hydrophobic and non-wetting polymer. PTFE is one of very popular coating component of guidewire and comes in varieties (Dunne et al., 2015). Moreover, it is electrical stable and has low friction. PTFE, with increasing temperature, is thought to be inert and non-toxic (Sajid et al. 2017). The amount of PTFE coating on specific material determines the non-stick and friction properties of that material. As a high chemical resistance, PTFE is perfect for use in chemical processing and storage applications because of its characteristic. As much as it is weather resistant, it is also biocompatible which makes this substance very beneficial in many medical applications. Due to its biocompatible property, it does not react with tissue and vein. Corona Plasma treatment is a surface modification process that is conducted on the surfaces of metals to change its surface properties like friction, thermal conductivity, and adhesion. However, PTFE is also subject to wear. Roughening methods and priming coats are frequently used to improve adhesion by enabling PTFE to chemically and physically bond to the surface (Saisnith & Fridrici, 2021). PTFE particles also have ability to store electric charges (Bu et al. 2013) .Hydrophilic Coating (HPC) is term categorized under Polyvinylpyrrolidone (PVP) coating. In contrast to PTFE, PVP coating is relatively an easier process as compared to proximal (PTFE) coating. This is because hydrophilic polymers easily break and penetrate the surface (Zhou et al. 2018). Therefore, most PVP coated wires are less stable and do not produce desired results for biomedical purposes (Ding et al., 2021).

Corona discharge treatment is used to coat bare wire with PTFE and PVP (HPC) coatings. It can be easily applied by applying high voltage through tip of electrode towards to surface of bare wire (Park et al., 2023). Controlling the corona process is key element as any inconsistency or fluctuation in the process may not meet the coating requirements. The electrode needles are maintained at a certain distance to provide smooth flow and charged with positive voltage (Nippatlapalli et al. 2022). The lubricity and smoothness of hydrophilic coating is always taken in considerations while defining the quality of guidewire distal section (Chopra et al., 2017).

3. Methods

This study, for the most part, will use quantitative design to investigate the guidewire coating test failures. First, aged, and real time samples were tested, followed by dry runs. Samples used in this paper were collected from three different lot and respective batch numbers. The participants in the testing conducted for this paper are trained at different levels and the training records of operators involved in this paper will be studied as a part of investigation and potential root cause of test failures. The collected data will be analyzed for defined hypotheses in the problem statement. As a part of examining Pressure Guidewire proximal and distal coatings, samples will be studied under Scanning Electrode Microscope (SEM), for both tested and untested samples. The coating parameters used during coating process of Pressure Guidewire will be used to create factorial design using Minitab software and optimal settings will be determined for coatings that can withstand and pass the lubricity testing without damaging the coating. A confirmation experiment will be conducted to check the positive results. The study will be limited to samples from three lots and batch numbers as mentioned above. The data obtained from dry runs won't be included in the DOE. The coating data will be collected only through SEM. The coating parameters under study are only obtained from one manufacturing site.

3.1. Lubricity Testing Method

A 24cm piece of proximal and distal wire is cut precisely. Wire is loaded into clamp in the upper assembly and the lower end is placed in space between two grips which is submerged into saline beaker. Each sample is tested for 5 cycles and results is represented as average of 5 cycles. For testing PTFE proximal tubes, two samples are randomly over the wire as shown in Figure 4 so that the wires come from different locations on the wire each time. This provides a better representation of the coating measurements and variability. When testing HPC distal tubes from the device, cut one 24cm sample, leaving approximately 1 cm of the proximal tube attached to the distal tube. This allows a more secure grip for the clamp to hold the part securely in place for the duration of the tests.

3.2. Initial Investigation

To investigate to testing failure, a cause-and-effect diagram was established and all potential causes of nonconformance were identified as shown in the figure 1 below. Different settings were used to examine the machine and

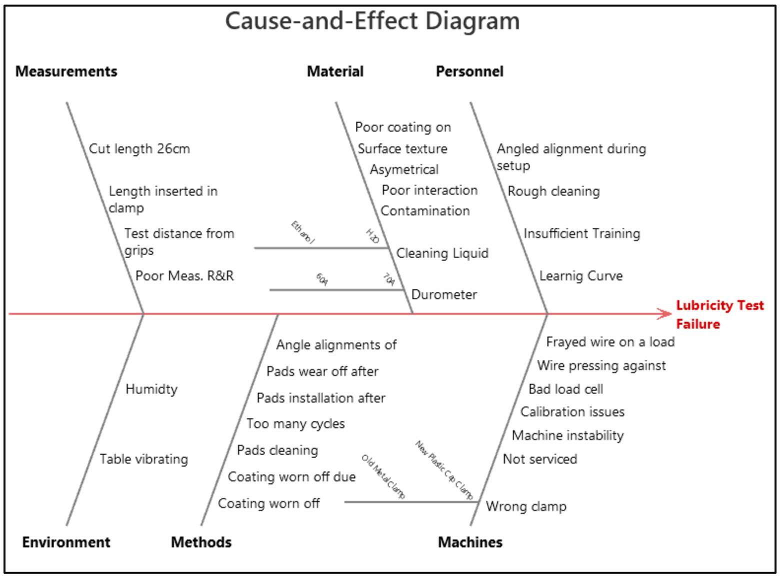

Figure 1. Cause-and-Effect Diagram

validate the test method. The calibration issues of the machine were fixed after performing the preventive maintenance work order and replacing the existing load cell with new one. To collect further evidence regarding factors contributing to test failures, trainings of all operators were determined. This included monitoring their practices, data collection, machine handling and operator to operator variations. During investigation, minor changes were noticed, for instance, prior to inserting the sample in the clamp, some operators wipe the sample with ethanol and inserted right away while others inserted after an average delay of 20 seconds. In the first case, the sample is inserted and submerged into saline beaker while it is still wet. In the latter case, due to delay, the sample is dried and inserted into the clamp and submerged into the saline. To understand the impact of different operators performing similar test, a Gage R&R study was conducted. The primary purpose of this study is to find differences between operators performing similar tests on same set of samples. Three operators were chosen, these include an unexperienced, moderate experienced and high experienced. 5 (T=0 years) proximal samples were prepared. These were first tested by all three operators, before retesting the sample set of 5 samples again in the second round. Set up recipe was used as these were proximal samples (See Table 1). The results were collected and analyzed. As it can be seen in the Figure 2, the results significantly varied operator to operator. Operator one (unexperienced) tested 5 samples and got average tensile force of 90-gram force. The same set of samples were then tested by operator 2 (moderately experienced), this time the average tensile force came out to be closer to 50-gram force. Upon testing the same set by operator 3 (experienced), the average tensile force was 100-gram force. For the second round of testing, same set of samples were tested with set testing parameters however this time, results varied significantly. The resulting forces of each sample fall within range of 270-gram force to 300-gram force. The results of operator 3 testing the same samples for the second time raised many concerns when the operator managed to get same results as round one testing, with average force closer to 100-gram force.

It was noted that there were no differences in following step to step test method procedures, this includes each operator calibrating the machine prior to testing. However, minor differences might have impacted the results. These include the way how each operator installs durometer on grips, ethanol wiping time, and inserted sample wire into the clamp (center or side wise). Another factor that may have caused variations between the results of three operators is how much percentage of error did each operator see during calibration

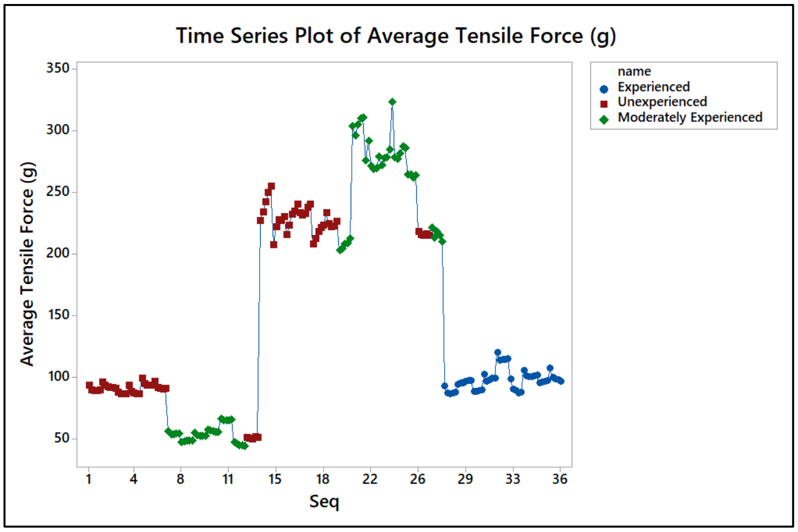

Figure 2. Time Series Plot

3.3. Coating Investigation

3.3.1. Proximal Side

To investigate the coating of T=0 years and T=2 years samples, Scanning Electron Microscope (SEM) was used to get closer look at the coatings of different samples. SEM throws high beam of electrons to capture the micro details of wire coating, typically up to million times closer. The images then gave out new information about various sections of wire, including the ones which were between grips of DL1000 machine during testing. These were then compared to non-tested samples and investigated further. The proximal coating, PTFE is hard coating. Samples can be re-tested multuple times and get similar average tensile value. The tested sample (T=2years) coatings in the figure 3 and figure 4 showed rough and coarse surface. This indicated that the accelerated aging process did wear down the PTFE coating which should not be the case. The results also showed multiple holes on the coating surface. The corona treatment parameters used to coat PTFE on the surface of bare proximal wire weren't enough to hold the wire within specification for 2 years time. The figure 5 and 6 below show the thickness of PTFE coatings on proximal section of Pressure Guidewire bare wire. Note that amount of coating depends on the corona treatment time and dip speed.

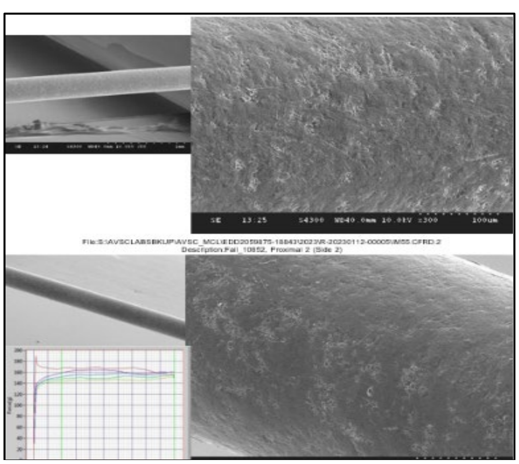

Figure 3. Failed Proximal section of Guidewire 1

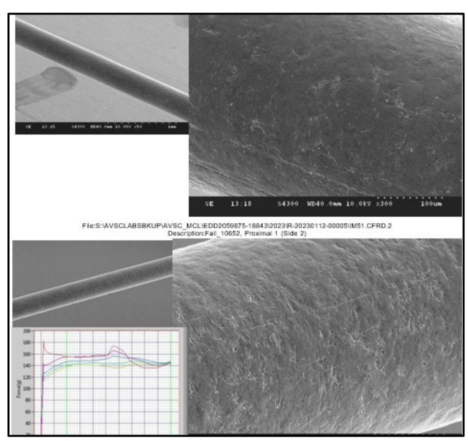

Figure 4. Proximal section of Guidewire 2

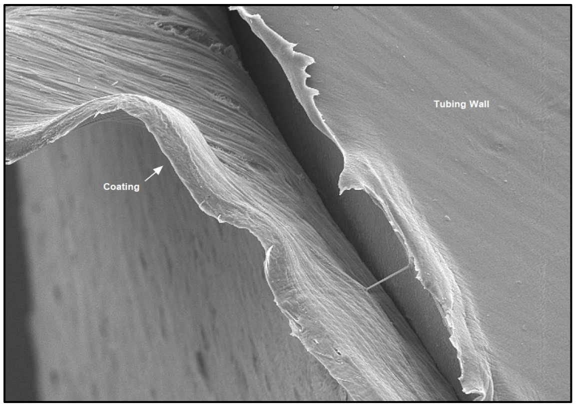

Figure 5. Proximal coating 1

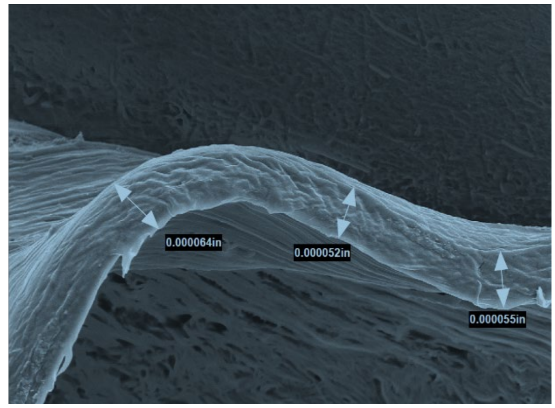

Figure 6. Proximal coating 2

3.3.2. Distal Side

Distal tubes are coated with PVP. As compared to PTFE, PVP coatings subside during every cycle of lubricity test. The Figure 7 and 8 above show the signs of silicone pads wearing the coating off during cycles. Upon further investigation, the figure 9 below, focusing up-to 10.0um showed the coating of T=2 years samples wore during lubricity testing.

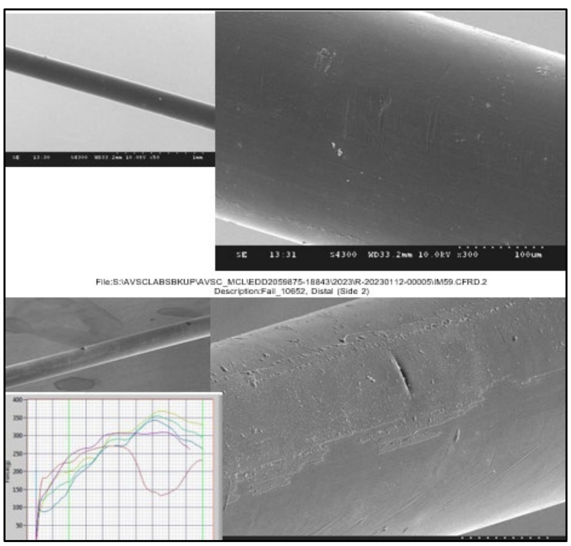

Figure 7. Distal section of Guidewire 1

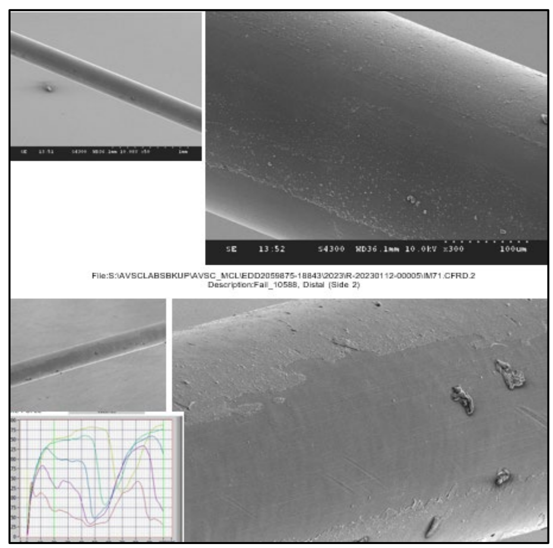

Figure 8. Distal section of Guidewire 2

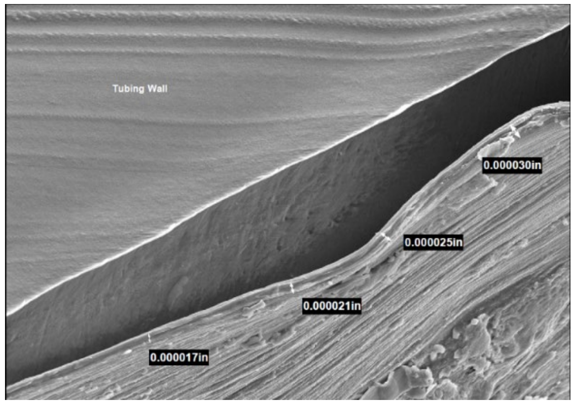

Figure 9. Distal coating

4. Results and Discussion

4.1 Proximal Experiment

Two factor, full factorial (DOE) on (i) Corona distance and (ii) Dip speed using 3 replicates was executed and results were analyzed. Main effects and interaction plot can be seen in figure 10 and 11. The Pareto chart figure 12 of standardized effects showed that corona distance, dip speed and the interaction of corona distance and dip speed to be statistically significant at the 0.05 alpha level. Corona distance exhibited the greatest effect on coating lubricity with an effect of 88.9 grams. Dip speed had a less significant effect; however, the interaction of corona distance and dip speed was significant. Through the experiment, it was found out that upon increasing the density of electron discharge, better results were achieved. Therefore, at the corona distance of 2 and dip speed of 30 seconds, the coating was found to impeccably coated, therefore, this was chosen as the optimal setting for corona treatment for proximal section of Pressure Guidewire.

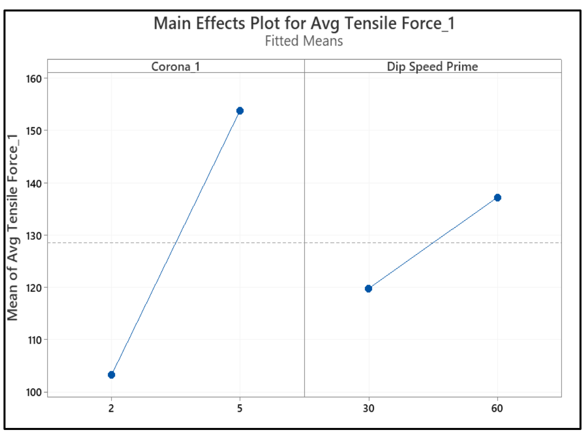

Figure 10. Main Effect Plot

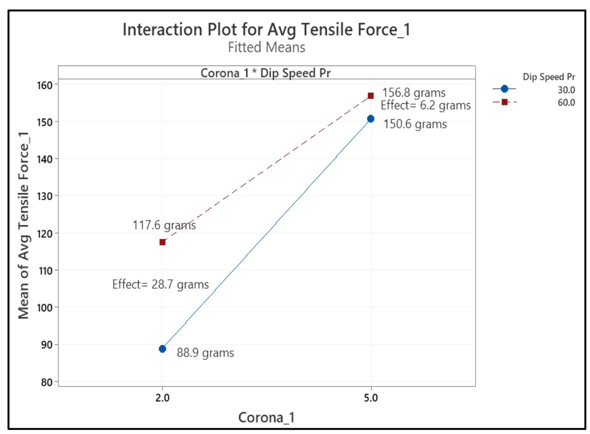

Figure 11. Interaction Plot

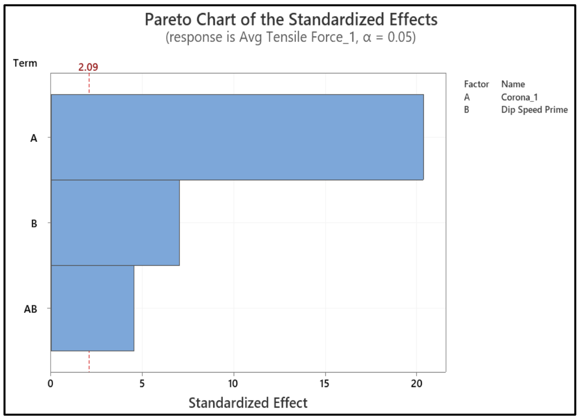

Figure 12. Pareto Chart

4.2 Distal Experiment

Figure 13 shows the Main Effects of UV Intensity and Corona Time on the experimental response ATF2. Changing the UV distance from 2inch to 6in achieved 51.7 grams reduction in average tensile force, from 92.5 grams to 40.8 grams, therefore bringing the quality characteristics within specification limit of 50 -gram force. This is consistent with the ANOVA p-value of 0.000 obtained for UV Distance. Alternately, Corona time factor did not have significantly effect on the average tensile force (p-value= 0.123) and the 4-gram effect is attributed to experimental and measurement noise. The Figure 14 shows that the Corona Time of 30 seconds and the UV intensity of 6.0 proves to be the most optimal setting for distal section of the Pressure Guidewire. The Pareto chart 15 displays the standardized effect of each experimental factor on the lubricity of the distal member, factors which exceed the critical t-statistic had a statistically significant effect on average tensile force. In this experiment, UV distance had the greatest effect on average tensile, whereas corona time did not affect average tensile. However, the interaction between UV distance and corona time also had a statistically significant effect.

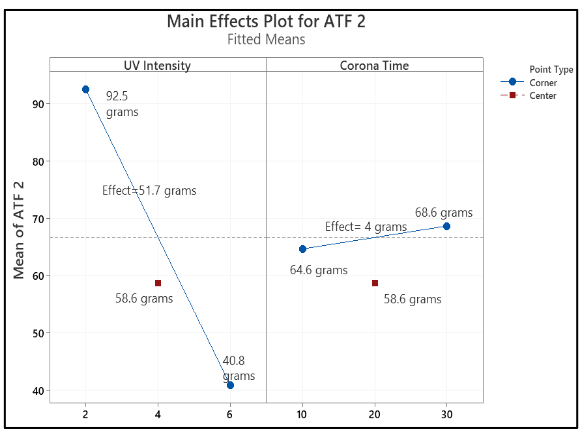

Figure 13. Main Effect Plot

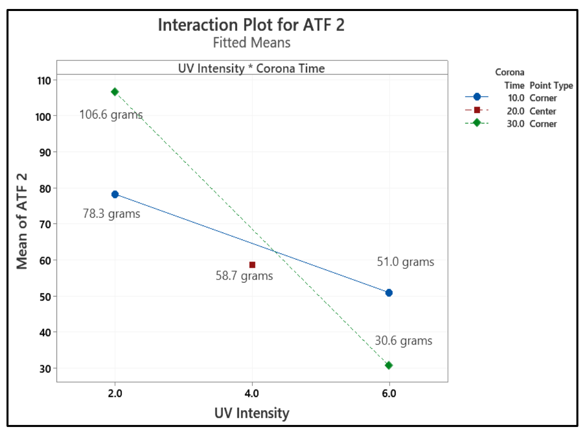

Figure 14. Interaction Plot

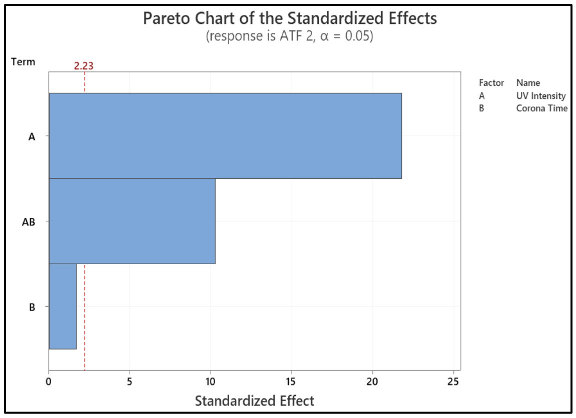

Figure 15. Pareto Chart

4.3 Corona Treatment

Distance of corona electrode from the guidewire was changed, it was shifted from an electrode distance of 5mm to electrode distance of 2mm; By making the electrode distance smaller, we made the part closer to electrode which increased the amount of plasma discharge applied to guidewire which modified the surface more and made it more receptive to coating. In addition to corona, we varied the dip speed from 30 in/min to 60 in/min. Since rheology studies of the PTFE coating showed the solution was non-Newtonian, it was noted that shear rate may have a significant effect on guidewire.

In short, we decreased the distance btw the corona electrodes and guidewire to increase the plasma density and provided stronger pre-treatment which improved the wire's ability to receive the coating.

4.4 Gage R&R

Due to the destructive nature of the tensile strength measurement process, each of the ten "samples" consisted of a set of eighteen wires which were prospectively prepared by the assessor to have homogeneous properties:

- Samples 2,4,6, and 8 were coated two times to increase their lubricity, this was done to challenge that the measurement process can differentiate parts having different friction levels
- Conversely, samples 1,3,5,7,9 and 10 were treated with the standard coating process to achieve routine average tensile strength results.

Gage R&R (Nested) for Avg Force

Source	DF	SS	MS	F	P
Operator	5	1301.2	260.239	1.1376	0.352
Sample ID (Operator)	54	12352.7	228.753	81.8107	0.000
Repeatability	120	335.5	2.796		
Total	179	13989.4			

Figure 16. Gage R&R for Average Force

Gage Evaluation

Source	StdDev (SD)	Study Var (6 × SD)	%Study Var (%SV)	%Tolerance (SV/Toler)
Total Gage R&R	1.96104	11.7662	22.04	24.50
Repeatability	1.67216	10.0330	18.79	20.89
Reproducibility	1.02448	6.1469	11.51	12.80
Part-To-Part	8.67865	52.0719	97.54	108.41
Total Variation	8.89745	53.3847	100.00	111.14

Number of Distinct Categories = 6

Figure 17. Gage Evaluation

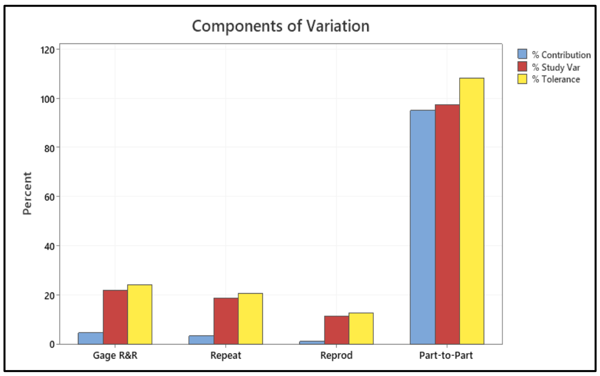

Figure 18. Component of variation

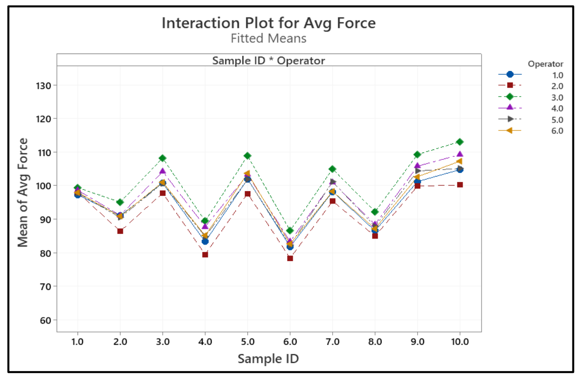

Figure 19. Interaction plot for average force

Each operator was randomly presented with test wires from each of the 10 groups and the process repeated for a total of 3 measurements per part for the six operators. The ANOVA for the measurement system data shown in Figure 16, indicated a p-value of 0.352 as Gage R&R for Operator which is not significant at the 95% confidence level. Alternately, the operator x parts interaction exhibited a p-value of 0.000 which indicates that the parts themselves have a significant effect on the overall variation. Figure 17 shows the total Gage R and R, and the repeatability and reproducible components to total Gage R and R. The total Gage R and R is the root mean square of the repeatability (20.89%) and reproducibility (12.80%). Repeatability is the variation obtained when an operator repeatedly measures a sample, and the reproducibility is the variation attributed to different operators measuring the same samples. In this analysis, a total Gage R and R of 24% which is acceptable per company's requirement of less than 30% total Gage R and R. Figure 18 provides a bar chart of the repeatability, reproducibility, and total Gage R & R and underscores that most of the variation (76%) comes from the actual differences in the parts rather than the operators. The graphical depiction of the data in Figure 19 is consistent with a measurement system that has good (i.e., low) repeatability and reproducibility as it shows operators obtain close average tensile force values.

The similarity of measurement readings operators obtain on the 10 parts can be seen in the operator x parts interaction plot for the measurement systems analysis data. In this figure, each plotted point represents the average of the three readings obtained by each of the six operators for each of the 10 samples. The fact that the average tensile force readings exhibit an operator-to-operator range of about 10 grams on each of the 10 samples underscores the acceptable level of repeatability and reproducibility.

4.5. Graphical results of Validation Study

4.5.1. Proximal Validation

Old setting: Corona distance 5mm and dip speed 60mm/min
Optimized setting: Corona distance 2mm and Dip speed 30mm/min

The figure 20 and 21 below show the probability plot and process capability for new optimized setting as well as figure 22 and 23 for existing (old) setting for proximal section of guidewire coating.

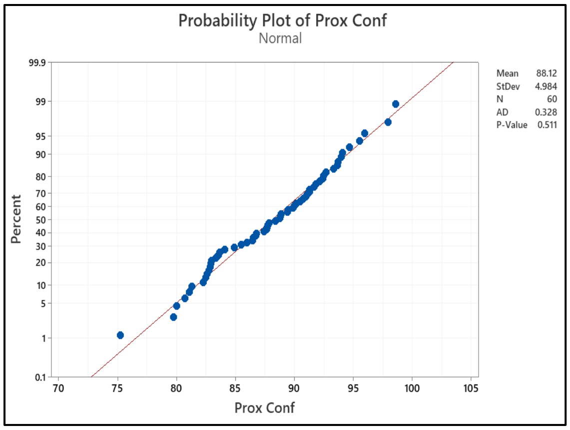

Figure 20. Probability Plot (Optimized Setting)

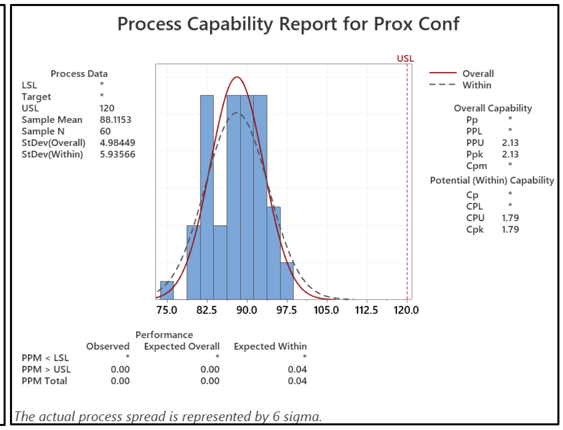

Figure 21. Process Capability (Optimzed Setting)

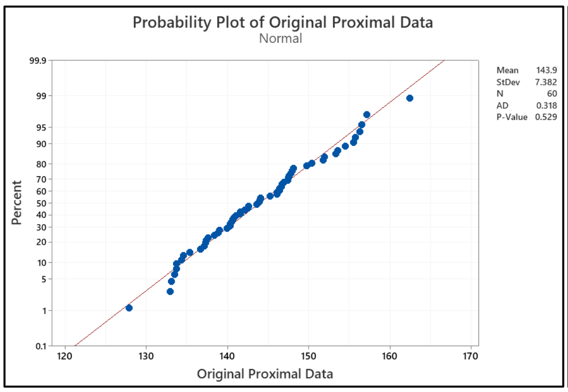

Figure 22. Probability Plot (Old Setting)

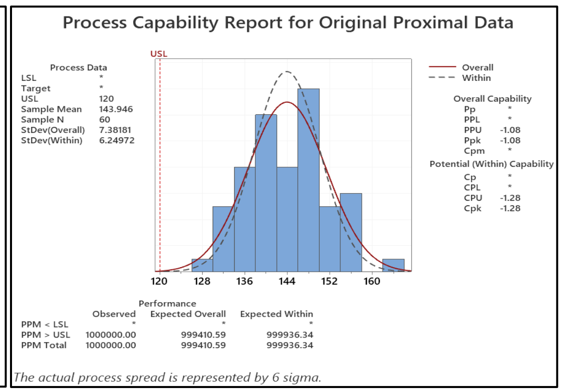

Figure 23. Process Capability (Old Setting)

4.5.2. Distal Validation

Old setting: UV 4.0 and Corona Time 10seconds.
Optimized setting: UV 6.0 and Corona Time 30seconds

The figure 24 and 25 below show the probability plot and process capability for new optimized setting as well as figure 26 and 27 for existing (old) setting for distal section of guidewire coating.

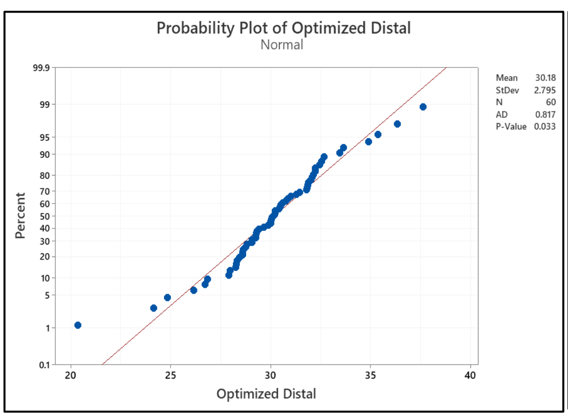

Figure 24. Probability Plot (Optimzed Setting)

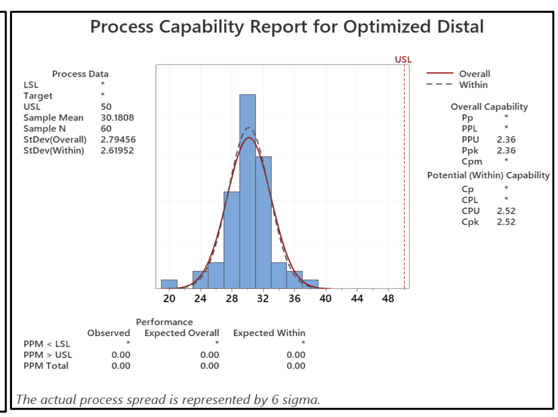

Figure 25. Process Capability (Optimzed Setting

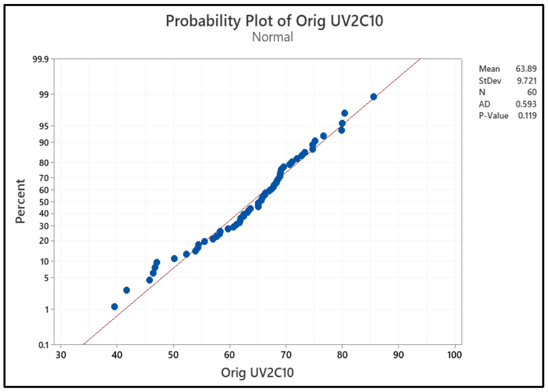

Figure 26. Probability Plot (Old Setting)

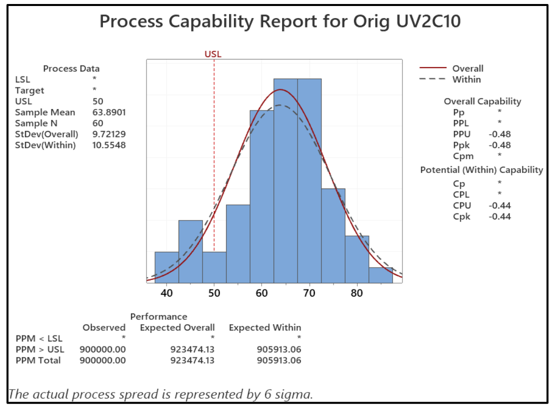

Figure 27. Process Capability (Old Setting)

4.6 Results

The in-depth investigation for lubricity testing failure highlighted all the potential errors showed in fishbone diagram. The calibration of lubricity tester showed inconsistency and was causing a potential hurdle to conduct testing and achieve results that can be further studied. The initial Gage R&R highlighted how the results varied from operator to operator. The SEM investigation discovered potential root cause. The coatings of T=0yrs and T=2yrs distal and proximal sections from certain lot and batch numbers appeared to be worn off. The two factor, factorial design for proximal and distal sections of Pressure Guidewire for both passed and failed samples showed how the corona plasma treatment time, corona distance, dip speed and UV intensity can affect the coating. For proximal section, the corona distance of 2.0mm and 30mm/min proved to be the optimal setting. For distal section, the corona time of 30 seconds and UV intensity of 6.0 demonstrated ideal results during lubricity test. To investigate the measurement process, a second Gage R&R was carried out systematically. The results of Gage R&R showed 24.50% effect on the process, which is lower than the company's 30% limit. A confirmation study was conducted with 60 samples and process capability analysis showed that the new optimized setting from DOE showed that the process is well in control and samples passed all the testing. A confirmation study was conducted with 60 samples and process capability analysis showed that the new optimized setting from DOE showed that the process is well in control and samples passed all the testing. Therefore, based on Table 1 from the problem statement, we reject the null hypothesis for proximal and distal sections of the Pressure Guidewire.

The coating wearing off from T=2 samples was turn out to be significant discovery. As compared to man and machine factor, material was more challenging concern. From patients' safety point of view, this was ranked 3 out of 4 on company's RAM. It was found out that during the accelerated ageing process, the original coating setting did not prove out to be sustainable with the Pressure Guidewire and therefore, recalling all products from failed lot and batch numbers. The DOE conducted showed how the coating process behaves on different settings. The original and the optimized setting for both proximal and distal sections of Pressure Guidewire did impact under both conditions of real time accelerated time. The thickness is coating peeling off from wires under the SEM showed lack of coating material. The durometer (60A, 70A) used during the testing are chosen according to standardized coating setting, therefore, wires tested with worn coating show different average tensile force however there was no effect of using old and new clamp. Through two factors DOE experiment, it was found out that the old setting for proximal section, corona distance of 5.0mm and dip speed of 60mm/min was found out of specification limit. The interaction plot showed the new optimal setting to be corona distance of 2.0mm and dip speed of 30mm/min. Therefore, the closer the nozzle and slower the speed, better coating thickness was achieved when the samples were aged artificially to T=2yrs. Similarly, the old setting for distal coating, UV intensity of 4.0 and corona time of 10seconds was found to be out of specification limit. The newer optimal setting of UV intensity 6.0 and corona (plasma) time of 30 seconds showed that the coating was sustained during aging process. Changing UV intensity from 4.0 to 6.0 means the distance of plasma from the samples, therefore, lowering the intensity and increasing the time coating the wire much better.

The Gage R&R with six operators was conducted after fixing the coating. The p-value of 0.352 (>0.05) was achieved, showing that the operators were not significant at the confidence level of 95%. The results of different operators testing different samples of similar nature followed a streamline pattern, hence proving different operators passing lubricity testing. The machine error was fixed through performing preventive maintenance work order.

5. Conclusion

This study provided detailed analysis on different factors that contributed the lubricity testing failure. The measurement system, human factor, and machine, all contributed to testing failure to a certain extent and the variance was calculated using DOE. Coating of Pressure Guidewire was the leading factor, as proved both through DOE and SEM images. This study helped essentially in fixing the coatings processes of guidewire and make the product more sustainable over the time.

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