Neuromodulation Leads Yield Fallout Improvement due to Fallen Segment

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Abstract — *Neuromodulation Leads used for Deep Brain Stimulation (DBS) is an elective surgical procedure in which electrodes (that generates electrical impulses that control abnormal brain activity) are implanted into certain brain areas. The leads consist in Ring Electrodes and a combination of Ring and Segmented. The electrodes are welded to the conductive wires using Resistance Welding technology. Epoxy adhesive is used at the electrode arrays to hold the electrodes in place and to provide stiffness for lead handling during implant. After each Epoxy Adhesive bonding process, the leads are Grinded to reduce the outside diameter. A failure is observed at the grinding process of the distal electrodes array when the segment electrodes detached from the assembly. An increase in Yield Fallout was observed during the implementation of a new Epoxy Adhesive. The objective of this project is to improve the yield performing a Resistance Welding Study that is expected to reduce the electrode detachment.*

Key Terms — *Epoxy Adhesive; Grinding process; Resistance Welding; Yield fallouts.*

PROBLEM STATEMENT

The historical yield fallout with the previous Epoxy Adhesive was about 2% and the new Epoxy adhesive showed yield fallout of 16.92%, resulting in a $20K increased in monthly scrap. Since no other process was changed as part of the Epoxy raw material implementation, it is believed that the adhesion of this new adhesive is causing the increased in yield fallout.

Research Description

The Neuromodulation DBS Lead required a Medical Adhesive material change that resulted in lower adhesion between with the distal segmented electrodes increasing the yield fallout due to fallen segments. This project intends to evaluate different process changes that could mitigate the impact of the new Medical Adhesive therefore resulting in scrap savings to BSCI.

Research Objectives

The objective of this study is to reduce the yield fallout due to segment electrodes detaching from the assembly during the Grinding process back to the original reject rate of 2%.

Research Contributions

The reduction of the reject rate will reduce product scrap dollars and increase line Final Yield and efficiency that will allow to meet production plan output.

LITERATURE REVIEW

West System noted that the Epoxy adhesive consists in the mix of a resin (Part A) and a hardener (Part B). Mixing epoxy resin and hardener begins a chemical reaction that transforms the combined liquid ingredients to a solid. The time it takes for this chemical transformation from liquid to solid is called cure time. As it cures, the epoxy passes from the liquid state, through a gel state, before it reaches a solid state.

"Open time and cure time govern much of the activity of building and repairing with epoxy. Open time dictates the time available for mixing, application, smoothing, shaping, assembly and clamping. Cure time dictates how long you must wait before removing clamps, or before you can sand or go on to the next step in the project. Two factors determine an epoxy mixture's open time and overall cure time: hardener cure speed and epoxy temperature" [1].

The warmer the temperature of curing epoxy, the faster it cures. Heat speeds up epoxy chemistry or the chemical reaction of epoxy components. The temperature of curing epoxy is determined by the ambient temperature plus the exothermic heat generated by its cure [1]. Ambient temperature is the temperature of the air or material in contact with the epoxy. Air temperature is most often the ambient temperature unless the epoxy is applied to a surface with a different temperature. Generally, epoxy cures faster when the air temperature is warmer.

Resistance welding is a thermo-electric process in which heat is generated at the interface of the parts to be joined by passing an electrical current through the parts for a precisely controlled time and under a controlled pressure, also called force [2]. To force the metals together, electrode pressure (force) provided by the weld head, is equally important. Miyachi Unitek noted that heat, generated by the resistance of the workpieces to the flow of electricity, either melts the material at the interface or reduces its strength to a level where the surface becomes plastic. When the flow of current stops, the electrode force is maintained, for a fraction of a second, while the weld rapidly cools and solidifies [2].

Resistance welding works by applying a large amount of current between two electrodes. As the current flows, anything between the electrodes is heated up due to its electrical resistivity [3]. The electrodes are often made from copper so that they do not heat up as much as the workpieces (low electrical resistivity), and they can also be water cooled. The major variables in resistance welding are the amount of current (amperage) and the weld time. Most resistance welding is used on thin parts, especially in sheet metal assemblies [3].

The DBS distal electrode array is a composite joint design where the segmented electrodes are held in place by the cable to electrode resistance weld and the Epoxy backfill applied under the carrier that contains the segmented electrodes.

The resistance welding process used for the DBS Neuromodulation leads uses a Copper Chromium Electrodes to weld the Platinum Core cables to the Platinum Iridium segments. The current Copper Chromium Electrode design has a Tip of 0.030” to perform the weld. Current Segment electrode design allows for a material contact interface of 0.048”. Therefore, part of this research will focus on how the increase in contact surface of the welded area impact the weld strength potentially improving the chances of the segment electrode to hold in place when exposed to the stresses caused during the Grinding process. Also, the Copper Chromium material of the welding electrode being use for the Resistance Welding process was verified using the Weldability Chart below [4].

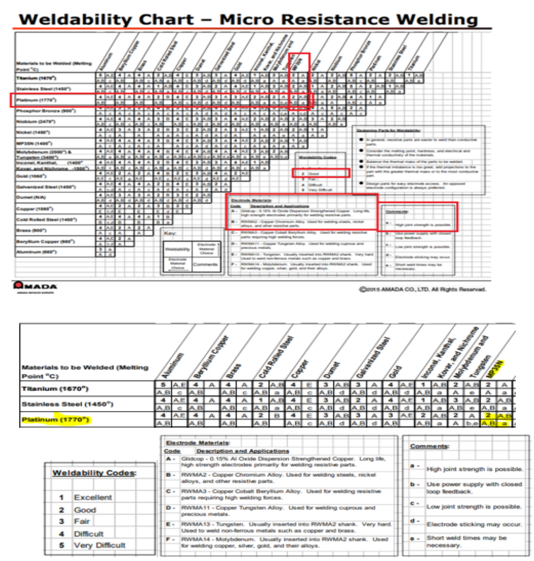


Figure 1
Weldability Chart for Micro Resistance Welding by Amada CO 2015 [3]

As it can be observed in the Weldability Chart, the Copper Chromium electrode material is suitable for welding the MP35 cables to the Platinum Segment Electrodes used in the DBS Neuromodulation Leads.

Grinding is machining process that’s used to remove material from a workpiece via a grinding wheel. As the grinding wheel turns, it cuts material off the workpiece while creating a smooth surface texture in the process. Grinding is a material removal and surface generation process used to shape and finish components made of metals and other materials. The precision and surface finish obtained through grinding can be up to ten times better than with either turning or milling. “Grinding employs an abrasive product, usually a rotating wheel brought into controlled contact with a work surface. The grinding wheel is composed of abrasive grains held together in a binder. These abrasive grains act as cutting tools, removing tiny chips of material from the work. As these abrasive grains wear and become dull, the added resistance leads to fracture of the grains or weakening of their bond. The dull pieces break away, revealing sharp new grains that continue cutting” [5].

During the Grinding process of the DBS Neuromodulation Leads, the OD is reduced from 0.065” to its final diameter of 0.050”. The process consists of a Stationary Wheel and a Moving Wheel that comes in towards the workpiece (the lead) at a constant velocity at a constant rotational speed. The equipment setup is as important as the process variables to ensure the workpiece is positioned at the right location with respect to the grinding wheel. This setup also ensures the grinding wheel is dressed and sanded appropriately to obtain a good finishing on the part and avoiding additional stresses applied to the part.

METHODOLOGY

Resistance Welding Investigation Research

The first step of the research was to manufacture two full leads, one of them will have all the segments welded to cables using the current resistance welding process and the other one will not have the segments welded to the cables. If a practical difference is found in the grinding performance during the inspection of these leads, a secondary part of the research was done. The second part will focus on how to improve the resistance welding strength expecting to overcome the reduction in the bonding strength caused by the change in the adhesive epoxy.

To increase the resistance welding strength an investigation was performed increasing the effective welding area between the cable and the segmented electrode. Increasing the effective welded area increases the maximum shear strength that the joint may be able to hold which would result in a better yield performance during the grinding process.

Following Boston Scientific Global Sampling Plan procedure for processes with Risk Index 1, 15 segment samples was used for this part of the research. The risk index is a measure of a potential harm to the patient due to a specific failure mode of the device. The risk index is calculated based on the severity and the occurrence rating of the potential harm caused by the failure mode per BSC Global WI Process Risk Analysis (PRA) procedure. Refer to Figure 2 below.

Risk Index Matrix

Occurrence Rating of Harm	Severity 1	Severity 2	Severity 3	Severity 4	Severity 5
5	0	1	2	3	3
4	0	1	2	2	3
3	0	0	1	2	3
2	0	0	1	1	2
1	0	0	0	1	1

Severity Rating

Calculation (Occurrence * Severity^2)	Risk Index Level
1 - 14	0
15 - 33	1
34 - 70	2
71 - 125	3

Figure 2
Risk Index Matrix per BSC Global PRA Procedure

BSC Internal Procedure Statistical Requirements for Qualification Procedure 97045435, requires that processes with risk index 1 requires a 95% of confidence that the population has less than 10% of defective rate. Refer to table 1.

Table 1
Confidence and Reliability % based on Risk Index for Variable and Attribute Data, as noted on Internal Procedure for Statistical Requirements for Qualification

Data Type	RI	Confidence	Reliability	LTPD†
	3	95%	99%	1%
	2	95%	95%	5%
Variable	1	95%	90%	10%
	N/A	Not Applicable		
	3	90%	99%	1%
	2	90%	95%	5%
Attribute	1	90%	90%	10%
	N/A	Not Applicable		

These samples were welded with the new welding electrode design with the optimized resistance welding area mentioned at Literature Review. The pull strength results from this samples were used to compare them to the pull strength results obtained from the previous Process Validation testing when the old design of the welding electrode was used. Also, the results were verified to meet the current axial strength product specification of minimum 0.5 lbf and the minimum Ppk of 0.69 required by the Boston Scientific Global Sampling plan procedure for the sampling size selected of N=15.

Table 2
Sample Size for LTDP 10% and Confidence of 95%, as noted on Internal Procedure for Statistical Requirements for Qualification.

Variable Plan – 1-sided			
n	Req. Ppk	AQL Ppk	AQL
15	0.69	0.94	0.24%
20	0.64	0.84	0.57%
30	0.59	0.75	1.24%
40	0.57	0.70	1.73%
45	0.56	0.69	1.99%
50	0.55	0.67	2.26%
60	0.54	0.65	2.62%
80	0.52	0.61	3.35%
100	0.51	0.59	3.84%
∞	0.43	n/a	n/a

After it is ensured that the product specification can be met with the new electrode design and its performance is equal or better than the older electrode design, 30 full leads were manufactured and grinded using the new electrode design. The grinding operation induces shear forces to the lead while removing material via the grinding wheel. The intent of this test was to verify if the increased in the effective welded area had an improved performance during the grinding operation overcoming the yield fallout caused by the change in Epoxy adhesive. The sample size of N=30 was selected taking in consideration the Internal Procedure for Sampling plan for Attribute that suggest a minimum of 22 samples, also the manufacturing constraint and high cost of the Neuromodulation Leads were part of the rationale. As discussed above, this process is a Risk Index 1. Processes with Attribute data and Risk Index 1 requires 90% of confidence that the population has less than 10% of defective rate, refer to Figure 4. The sample size of N=30 meets the Boston Scientific Global Sampling plan procedure of n=22, a=0 for processes requiring an acceptance level of Lot Tolerance Percent Defective LTPD0.10 ≤ 10% for Attribute data, refer to Table 3 below. Furthermore, each lead contains 15 segments which represent a total of N=450 if the total amount of electrodes is taken into consideration for the probability of failure of each unit. In other words, one full lead has 15 chances of obtaining one failure due to a falling segment, that will represent a scrap unit. Below table 2 noted that Parameter for Attribute Plans for 90% of Confidence are n=22, and a=0 per Internal Procedure for Statistical Requirements for Qualification.

Table 3
Attribute Sampling Plan for 90% of Confidence

90% Confidence – Attribute Plans		
Type	Parameters	AQL
Single	n=22, a=0	0.23%
Double	n_1=24, a_1=0, r_1=2, n_2=22, a_2=1	0.89%
Single	n=38, a=1	0.94%
Double	n_1=24, a_1=0, r_1=2, n_2=40, a_2=2	1.18%
Single	n=52, a=2	1.59%
Double	n_1=24, a_1=0, r_1=3, n_2=55, a_2=3	1.85%
Single	n=65, a=3	2.13%
Double	n_1=24, a_1=0, r_1=3, n_2=70, a_2=4	2.16%

All 15 samples use to evaluate axial strength were visually inspected and pull tested. The pull strength results obtained was verified to follow a

Normal Distribution to perform a Capability Analysis and determine a Process Performance Index (Ppk) and sample mean result. A Boxplot graph was used to visually verify if the data collected from the new electrode is different from the historical data that was collected from the Process Validation performed using old electrode design. The graph was use as a tool to assess and compare the shape, central tendency, and variability of sample distributions, and to identified outliers if any. If the new electrode results look equal or better than the older electrode, a set of distal lead samples was built up to the grinding process to verify if the fallen segment yield fallout is improved.

Minitab was the software use, to determine the Normal Capability Analysis to evaluate the potential and overall capability of the process based on a normal distribution. It was supported that the process can produce output that meets customer requirements. Also, Compare the overall capability of the process with its potential capability to assess opportunity for improvement.

For shear strength evaluation, the yield fallout at grinding of the 30 leads manufactured using the new welding electrode design was compared with the actual yield fallout of leads manufactured with the old welding electrode design. This sampling is based an Attribute data sampling plan for a process requiring an Acceptance Level of LTPD0.10 ≤ 10% per the Boston Scientific Global Sampling plan procedure. Also, with this sampling and the current reject rate of 16.92% observed it is ensured enough resolution to at least obtained a failure and be able to compare both populations. If there is a yield fallout from the 30 leads built with the new electrode design, a two-proportion test using Minitab was used to determine if there is a significant statistical difference when compared to the yield fallout observed from the population that used the older segment design. The sample of 30 units planned to use for this analysis is acceptable for sample size.

Cure Time Study (Epoxy Curing Time)

The research will study the effect of oven cure time increase using both epoxy old (as baseline) and New that could reduce the amount of segment electrodes detach during the grinding operation. This study was performed as exploratory test, for that reason the amount of sampling was limited due to the cost of the total study, each sample cost $1.6k, the total cost for all samples was close to $60k.

Four (4) groups of 10 distal end lead samples for each group was built up to the grinding process. The two (2) different Epoxies was used and was cured at 2 different curing times. The groups were as follows:

Table 4

New vs Old Epoxy Group by Cure Time hrs

Group	Samples	Epoxy	Ambient Cure	Oven Cure Time
1	1-10	Hysol	1 hr	3 hrs
2	11-20	Hysol	1 hr	5 hrs
3	21-30	BSC	1 hr	3 hrs
4	31-40	BSC	1 hr	5 hrs

Built distal sample and continue units up to Distal Epoxy Backfill process, Perform the corresponding Epoxy Backfill Curing, continue units up to Distal Grinding Process, Finally Record Inspection Results. The scope of the study consists in the evaluation of the effect that the cure time and the different Epoxies have on the segment electrodes detachment rate at the grinding process. A proportion test was conducted with the results of the grinding inspection to evaluate if there is a significant difference in yield fallout between the 4 groups. Minitab was used for the analysis and the key output includes the estimate of the difference, the confidence interval, and the p-value.

The confidence interval provides a range of likely values for the difference between two population proportions. For example, a 95% confidence level indicates that if you take 100 random samples from the population, you could expect approximately 95 of the samples to produce intervals that contain the population difference.

To determine whether the difference between the population proportions is statistically significant, compare the p-value to the significance level [8] Usually, a significance level (denoted as α or alpha) of 0.05 works well. A significance level of 0.05 indicates a 5% risk of concluding that a difference exists when there is no actual difference. If p-values for both Epoxy vs Cure Time are less than the significance level of 0.05, the decision is to reject the null hypothesis and conclude that the proportion of different cure time for Hysol and BSC Epoxy make a difference in the study.

Results and Discussion

As establish in the methodology section, the first study that was conducted to understand the welding effect on the joint force was the manufacturing of two leads, Lead A constructed using the current procedure and lead B constructed without the segments welded to the cables. The intent of this study was to process both leads at Distal Grinding. After the process were performed, both leads were visually inspected to detect missing electrode. The results showed that Lead B had all the electrode missing and Lead A has only one electrode missing. The interpretation of this study is that the cables to segment electrode weld potentially had significant interaction in the joint.

To confirm that new electrode design meets current product specification and behave equal or better regarding axial strength, 15 welding samples were pull tested, and visually inspected. These 15 samples were compared with 45 older samples created during process validation at Valencia and Dorado Site. In the previous process qualifications (PQ) the capabilities values (Ppk) for Dorado site were 1.74, and for Valencia site were 1.60. In the Capability Analysis for New Electrode Design show in Figure 3, it is observed that Ppk was 3.67 which shows an improvement when compare with 1.74 (Dorado Ppk) and 1.60 (Valencia Ppk), refer to Figure 4 and 5 respectively. Also, it demonstrated that the process with the new electrode design can consistently meet product specification of 0.5lbf and it met the Ppk of 0.86 minimum required by the Boston Scientific Global Sampling plan procedure.

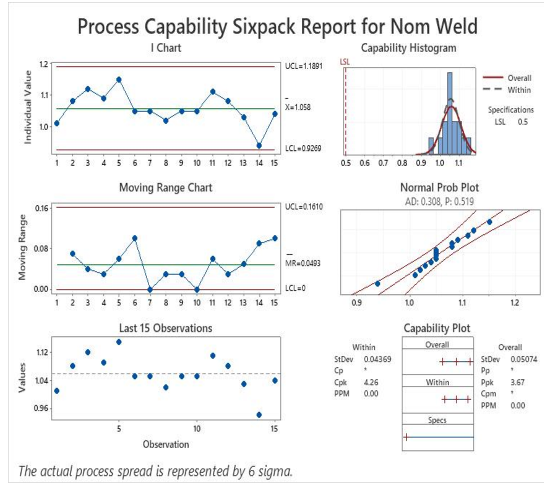


Figure 3

Capability Analysis for New Electrode Design

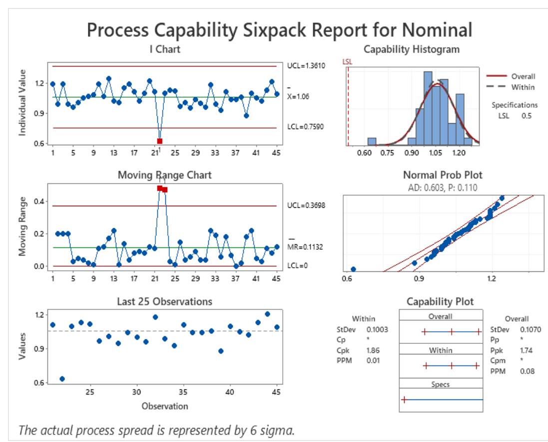


Figure 4

Capability Analysis Dorado OQ/PQ Report

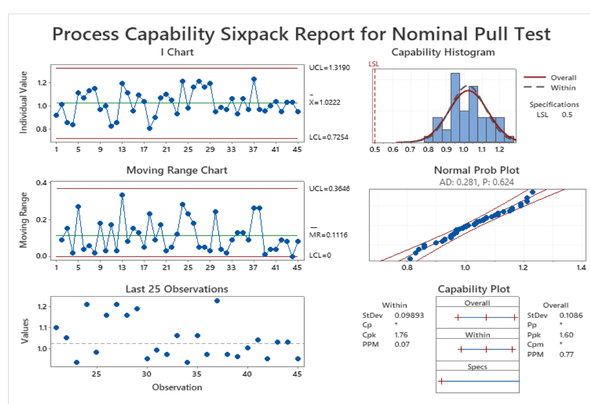


Figure 5

Capability Analysis Valencia OQ/PQ Report

The Anderson-Darling Normality test showed a P value> 0.05, therefore the data can be considered to follow a Normal Distribution. has Also, as it can be observed a process capability of 3.67 was obtained which meets the 0.86 requirement explained above. Generally, higher Ppk values indicate a more capable process.

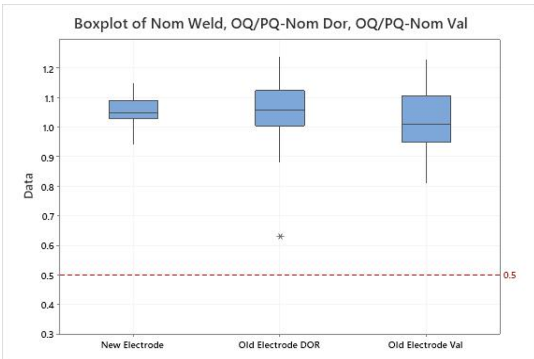


Figure 6

Pull Strength Boxplot for New Electrode vs DOR & Valencia old electrode

The boxplot data show in Figure 6 shows the pull test data gathered using the new electrode design and compared to the data gathered during the process validation when using the older electrode design. The sample size used for the new electrode design in the boxplot data shown in Figure 6 was the 15-welding sample described in previous sections. For Dorado and Valencia, the total welding sample was 45. A lower pull strength variation was observed when comparing the group of the data of the new electrode design against the older groups, and no outlier was identified.

After the test of the 15 welding samples was completed, the next step was to conduct a study using 30 full leads manufactured and grinded using the new electrode design. To confirm that new electrode design behaves better regarding shear strength. For that the 30 full leads with new electrode design were compared with the population of leads manufacture with older electrode design and using both epoxy (Hysol and BSC) during Distal Backfill process. This population and the 30 Full Leads manufactured with the new electrode design were visually inspected after Grinding process, and the identified nonconformities (NCs) were register in the system. The study for the older electrode design leads had data of units' process at Grinding with pass status or with NCs from week 1 to 21 of the year 2021. The 30 full leads manufactured with the new electrode design were process at Grinding in the week 21.

In Figure 7, it can be observed a table containing the information regarding Yield fallout of older and newer electrode weld design from week 1 to 21 of the year 2021.

Fallen Segment Yield Trending						
Week	Qty Scrap Unit Hyso	Qty Scrap Unit BSC	Qty Unit Grind-Hysol	Qty Unit Grind-BSC	Fallout-Hysol	Fallout BSC
1	12	0	41	7	29%	0%
2	1	0	21	0	5%	0%
3	1	0	30	8	3%	0%
4	0	1	0	40	0%	3%
5	0	0	0	0	0%	0%
6	0	0	0	16	0%	0%
7	0	1	0	34	0%	3%
8	0	0	0	38	0%	0%
9	0	0	0	13	0%	0%
10	0	0	0	17	0%	0%
11	0	1	0	16	0%	6%
12	0	2	0	49	0%	4%
13	0	1	0	31	0%	3%
14	6	0	61	0	10%	0%
15	16	0	48	0	33%	0%
16	0	0	0	4	0%	0%
17	0	1	0	29	0%	3%
18	0	0	0	0	0%	0%
19	0	0	16	0	0%	0%
20	4	0	14	7	29%	0%
21	5	0	35	0	14%	0%
	45	7	266	309		
	Yield Fallout Total		16.92%	2.27%		

Figure 7

Fallen Segment Yield Trending Table

In this table it can be observe that of a total of 575 of units were processed at grinding with the old electrode design and a total of 52 units were Scraped, this represents a total of 9% in yield fallout. But when the data is segregated evaluating old design using Hysol Epoxy and old design using BSC Epoxy. Table 5 explain the results are as follow, 45 units scrap contain Hysol epoxy, and 7 units scrap contain BSC epoxy, corresponding to 16.92% vs 2.27% in yield fallout respectively.

Table 5

Yield Fallout Hysol vs BSC Epoxy

	Hysol	BSC
Totals Scrap	45	7
Yield Fallout	16.92%	2.27%

The relevance of this comparison is to sustain the trending in yield fallout, stated in problem statement, caused by the change in epoxy raw material. This is the reason that led the investigation to look for ways of overcoming the yield fallout and returning it to the baseline, close to 2%.

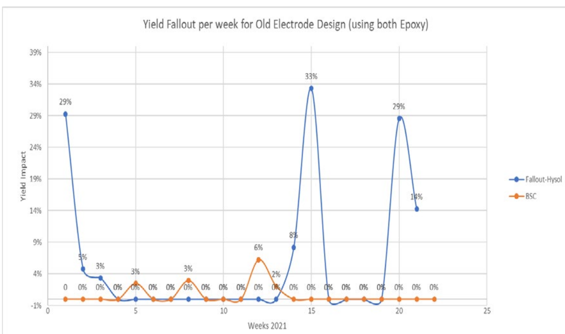
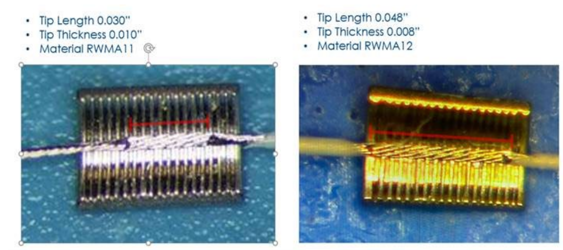


Figure 8

Yield Fallout per week

This graph presents a graphic comparison of the yield fallout for population of epoxy using the old electrode design. It can be clearly observed the higher peaks of Hysol Epoxy during weeks were units with Hysol Epoxy (Blue) are being built when compared to the weeks when units with BSC Epoxy are built (Orange), refer to Figure 4 for further details. It is important to clarify that in some weeks BSC Epoxy leads do not have production due to commercial demand.

As it can be observed in Figure 7, none of the 30 units that were welded using this new electrode and Hysol Epoxy on week 31 resulted with missing or fallen segment electrode after grinding. When comparing to the 35 units built with the older electrode and Hysol Epoxy that resulted with 5 units rejected due to fallen segment for a 14% of yield impact. Based on this data it can be concluded that increasing the effective welded area increases the maximum shear strength that the joint may be able to hold which would result in a better yield performance during the grinding process. Figure 9 below shows the welded area of the old electrode design on the left side and the new electrode design on the right side. As it can be observed, the new upper electrode design showed a significant increase in the effective welding area between the cable and the segmented electrode.



Old Electrode New Electrode

Figure 9

Old vs New Electrode Design

A cure time study was conducted using both Epoxy adhesives. The study consisted in building distal ends of units with both Epoxies. Each group of Epoxy units were divided into 2 different groups of curing time where the Oven Cure time was varied between 3 or 5hrs. The intent of the study was to verify if the increase in yield fallout due to the fallen segment caused by the change to the New Epoxy is related to incomplete curing. Also, the study was used to verify if the yield fallout can be reduced by increasing the oven cure time above the 4hrs that is currently allowed per current Work Instruction. A visual inspection was performed after the grinding operation is completed to evaluate the number of units that showed fallen segments (Failed Units) detached from the lead. The data collected showed that the cure time is not a significant factor since the number of failed units due to fallen segments from the units bonded with the New Epoxy was similar at both the 3hrs and 5hrs cure time, refer to Table 6 and Figures 11 and12 below for further details.

Table 6

Epoxy Group Description

Group	Samples	Adhesive	Ambient Cure Time (hrs)	Oven Cure Time (hrs)	Failed Units
1	1 -10	Hysol	1	3	5
2	11-20	Hysol	1	5	6
3	21-30	BSC	1	3	0
4	31-40	BSC	1	5	0

Test and CI for Two Proportions: Hysol vs BSC Epoxy (3hrs)

Method

Event: Failed Units_2 = Y
p_1: proportion where Failed Units_2 = Y and Epoxy_2 = BSC
p_2: proportion where Failed Units_2 = Y and Epoxy_2 = Hysol
Difference: $p_1 - p_2$

Descriptive Statistics: Failed Units_2

Epoxy_2	N	Event	Sample p
BSC	10	0	0.000000
Hysol	10	5	0.500000

Estimation for Difference

Difference	95% CI for Difference
-0.5	(-0.809898, -0.190102)

CI based on normal approximation

Test

Null hypothesis $H_0: p_1 - p_2 = 0$
Alternative hypothesis $H_1: p_1 - p_2 \neq 0$

Method	Z-Value	P-Value
Normal approximation	-3.16	0.002
Fisher's exact		0.033

The normal approximation may be inaccurate for small samples.

Figure 11

Two Proportion Test for Hysol and BSC Epoxy Cure Time=3hrs

The p value =0.002 confirm that the null hypothesis that there is a significant difference between Hysol and BSC Epoxy in terms of Failed units as establish in the Problem definition as the main cause for the Yield fallout.

Test and CI for Two Proportions: Hysol vs BSC Epoxy (5hrs)

Method

Event: Failed Units_1_1 = Y
p_1: proportion where Failed Units_1_1 = Y and Epoxy_1_1 = BSC
p_2: proportion where Failed Units_1_1 = Y and Epoxy_1_1 = Hysol
Difference: $p_1 - p_2$

Descriptive Statistics: Failed Units_1_1

Epoxy_1_1	N	Event	Sample p
BSC	10	0	0.000000
Hysol	10	6	0.600000

Estimation for Difference

Difference	95% CI for Difference
-0.6	(-0.903636, -0.296364)

CI based on normal approximation

Test

Null hypothesis $H_0: p_1 - p_2 = 0$
Alternative hypothesis $H_1: p_1 - p_2 \neq 0$

Method	Z-Value	P-Value
Normal approximation	-3.87	0.000
Fisher's exact		0.011

The normal approximation may be inaccurate for small samples.

Figure 12

Two Proportion Test for Hysol and BSC Epoxy Cure Time=5hrs

The p value =0 confirm that the null hypothesis that there is a significant difference between Hysol and BSC Epoxy in terms of Failed units as establish in the Problem definition as the main cause for the Yield fallout.

CONCLUSION

With the data collected through this study it can be concluded that the increased in the effective weld area between the cable and segment electrode increases the maximum shear strength that the joint can withstand during the grinding process. This improvement on the maximum shear strength that the new welding electrode provided proved sufficient to overcome the adhesion strength lost caused by the Epoxy material changed reducing the amount of unit scrap due to fallen segment at the Grinding operation. Also, the results from this study showed that the cure times of the different Epoxies is not as a significant factor as the Epoxy material change.

The contributions of this research project have been the sustained reduction in rejection rates, returning the yield fallout to below 2% (baseline of the process) instead of the 16.92% observed when the epoxy change. The study results lead to a more capable, repeatable, and reliable welding process. For that reason, less starts need to be made, giving the manufacturing line to be more flexible, having a better capacity to meet production plan output, this ultimately translate in a better net labor efficiency. After the change implementation a clinical build requirement of 236 units was performed, the result of yield fallout regarding fallen segment was 1.7% this represents a total of 4 scrap units for a cost of $6,400. If the process were having the previous yield fallout of 16.92% a total of 40 units should has been result in scrap for a potential total cost of $64,000.

The increase in the welded area between the cables and the segment electrodes effectively increase the capability of the electrode joint to withstand the shear stress caused by the grinding process. For future development of similar resistance welding processes, the effective welded area between the components must be as important output to be study as any other variable being study as part of the characterization phase.

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