

Coronary Guide Wires

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Abstract

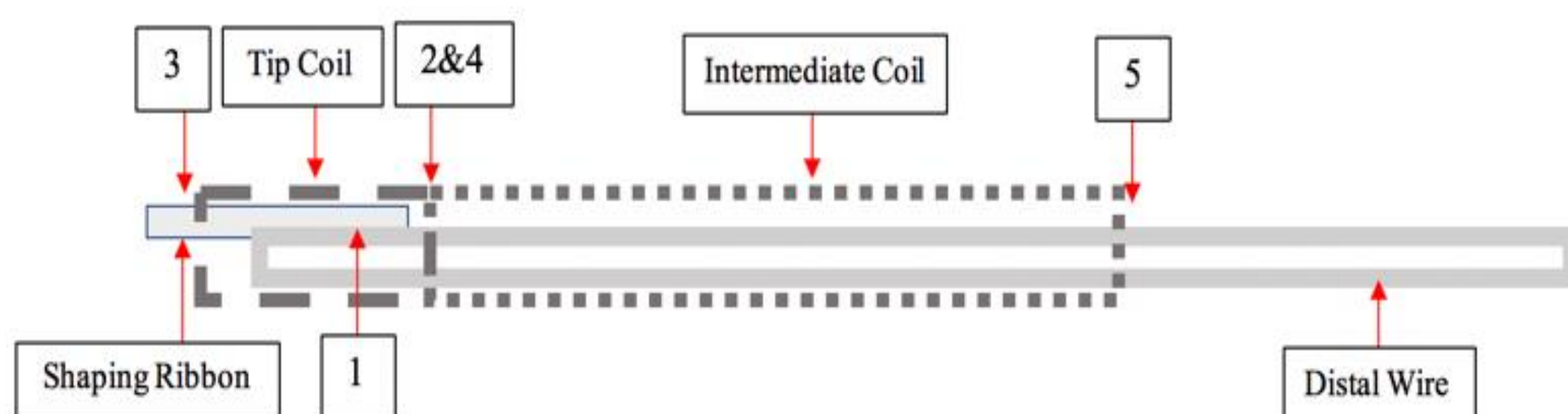
Within Abbott Vascular Balance Guide Wire Manufacturing, yield has been lowered due to material defects, specifically platinum and stainless steel coils. These defects related to coils were decreased. In quantified terms, coil defects were decreased to 0.2%. In addition, Balance Line Yield and Balance Soldering Zone Yield were increased by 1% individually. All coil specification preferences were determined and standardized within in-house Manufacturing Process Instructions. Due to increase in yield, Balance Manufacturing had an increase in production by 60 units. Consequently, Balance Manufacturing started saving \$203.40/day.

Introduction

It has been identified that the problems with the coil specifications come from the coil cutting and mishandling performed by operators. In addition, the specifications established in current Manufacturing Process Instructions are not the most efficient instructions and coil specifications for the operators to follow. Training for operators with modified Manufacturing Process Instructions was completed in order to minimize operator and process variances while creating standardized instructions on how to cut coils..

Background

There is a variety of guide wire models manufactured within Abbot Vascular known as Balance, Whisper and Universal. Therefore, different manufacturing processes are required. Balance Manufacturing, which is the focus of the project, has three different zones utilized to assemble and deliver the whole wire, which are: Soldering Zone, Adhesive Zone and Packaging Zone in that order. Within Balance Soldering Zone, there are four lines with six manufacturing stations in a specific order where each one has a different task to complete: Tack Solder (1), Tip Attach (2), Tip Solder (3), Center Solder (4), Proximal Solder (5) and Wire Inspection, in that order. Balance Manufacturing yield has been lowered due to defects of coils identified at Soldering Zone Tip Attach station.



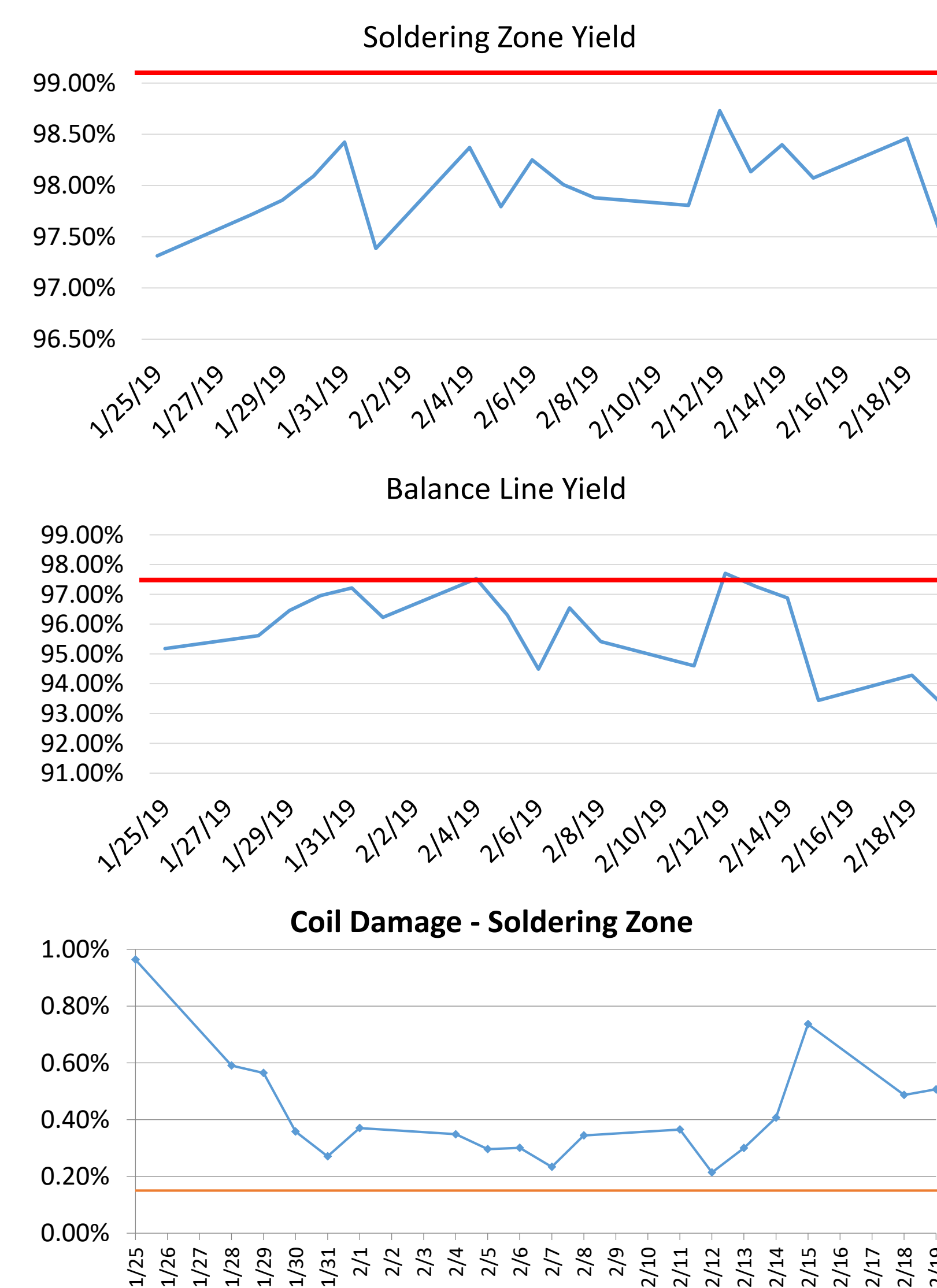
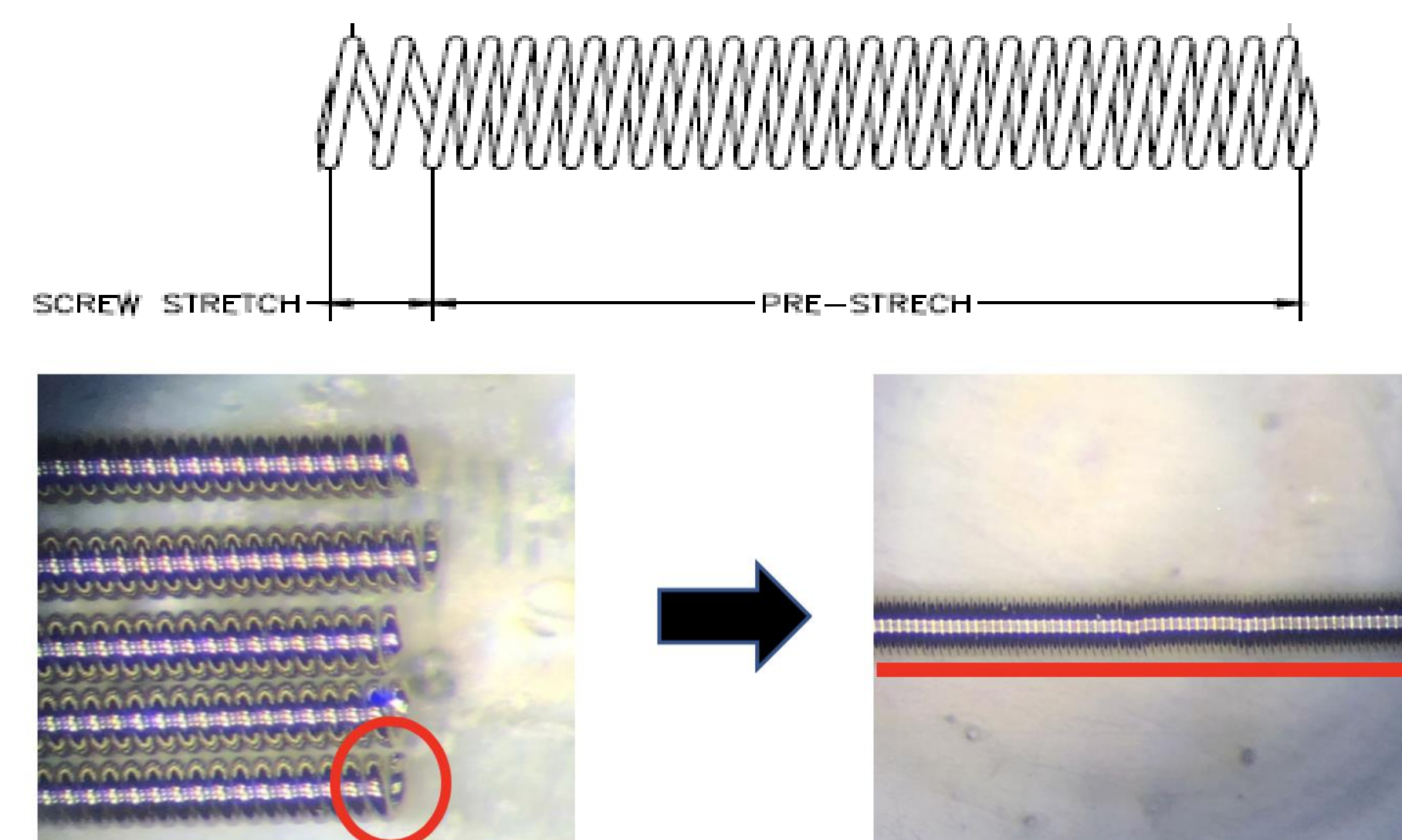
Problem

It has been acknowledged that, due to operator-related manufacturing procedures, the two coils (tip coil and intermediate coil) are arriving with defects and unwanted specifications making the operator's task difficult and occasionally causing wasted material. Therefore, Balance Manufacturing yield is lowered due to the amount of waste being registered at Soldering Zone.

Methodology

Define	<ul style="list-style-type: none"> • Problem Statement • Project Objectives • Project Contributions
Measure	<ul style="list-style-type: none"> • Schedule • Material Specifications • Material Performance (Yield)
Analyze	<ul style="list-style-type: none"> • Root Cause Analysis • Confirmation Run
Implement	<ul style="list-style-type: none"> • Hourly Monitoring Program • SA Operator Training • Manufacturing Process Instructions Modification
Control	<ul style="list-style-type: none"> • Monitor FG Balance Performance

Operator's task will be dependent of the tip and intermediate coils variables. Each variable has its own specification already established in current Manufacturing Process Instructions. Soldering Zone Yield and Balance Line Yield were monitored as for a period of time. The Balance Line Yield only met its target of 97.5% twice having an average of 96.1% and Soldering Zone Yield never met its target of 99.1% having an average of 98.0%. As for coil damage percentage, during this period, it never met its target of 0.2%.



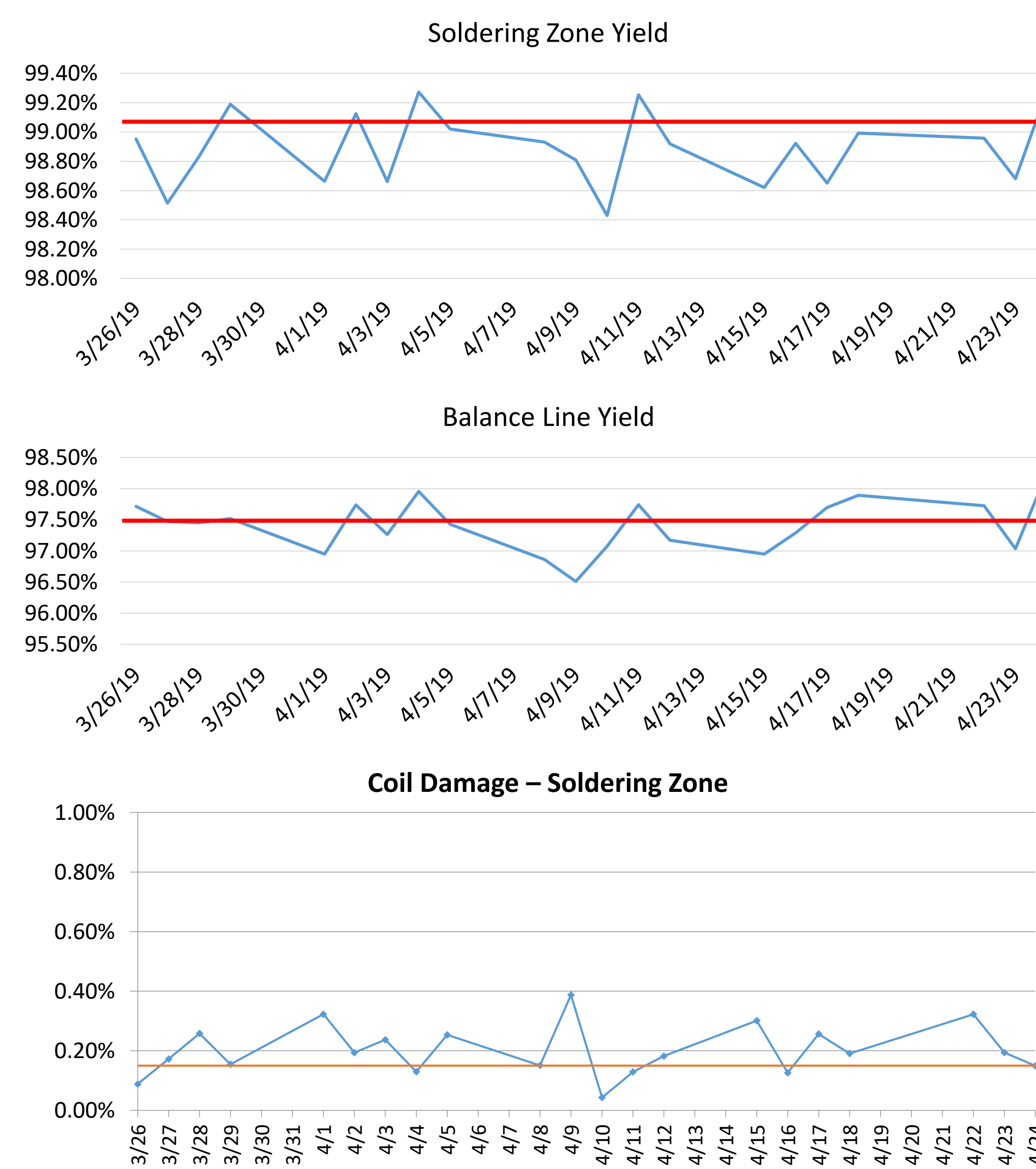
Results and Discussion

In order to avoid operator mishandling the units during the soldering process, an Hourly Monitoring Program was created to observe information of how the soldering zone behaves. Furthermore, by accumulating these hourly data, the manufacturing engineer will have a better understanding of which hour the operators are more likely to register Coil Damage or any other scrap data. With this information, the manufacturing engineer can react in a timely matter to solve why there was a Coil Damage registered by knowing the peak hours of scrap data.

	Accumulative Yield Per Hour							
	Hours							
Production	8813	13409	13478	6864	12224	13127	12961	9733
Scrap	111	162	141	94	109	137	130	134
Yield	98.8%	98.8%	99.0%	98.6%	99.1%	99.0%	99.0%	98.6%
Target	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%	99.1%

1st shift operators have better performance than 2nd shift operators. Therefore, Cross-Training between both shifts was initiated. One operator from the 2nd shift was brought down to 1st shift to establish a learning dynamic with the 1st shift operators. They shared techniques, suggestions were given and test runs were performed by the 2nd shift operator to be evaluated by the 1st shift operators. After successfully training one 2nd shift operator, this operator shared all the acquired knowledge with the other 2nd shift operators. Hence, Cross-Training was completed.

In order to make coil cutting Manufacturing Process Instructions for Balance Manufacturing error-proof, the format was reconfigured, instructions were modified and figures were added to make the instructions more graphic. After implementing all these changes, the approval of the operators was received to make the new Manufacturing Process Instructions an official document.



Conclusions

Balance Manufacturing accomplished an efficiency improvement in three evaluations: Line Yield, Soldering Zone Yield and coil defect percentage. Coil Specifications were standardized, which minimizes inconsistencies between SA and FG Balance. In addition, Cross-Training between SA 1st shift and 2nd shift also decreased inconsistencies between operators. Modifications to current Manufacturing Process Instructions will help future operators have a better understanding of the adequate manufacturing process. These improvements will continue to be monitored in order to avoid any possible rework. Balance Manufacturing had an increase in production by 60 units. Each unit costs \$3.39 to be produced. Consequently, Balance Manufacturing started saving \$203.40 per day due to the 1.3% increase in yield. Assuming only 5 working days per week and continuous yield, it is equivalent to \$1,017 per week and \$52,884 annually.

Future Work

Balance Manufacturing will continue to be monitored to assure that yield will no longer have a high impact due to defects related to coil specifications or mishandling by operators. After having operator approval for the modification in Manufacturing Process Instructions for coil cutting, administration approval will be persuaded to make the modified Manufacturing Process Instructions an official document for future generations within engineering and operations.

Acknowledgements

Within Balance Manufacturing, most support was provided by the operators. They perform the tasks, therefore, they are the experts that shared knowledge in manufacturing processes specifically for guide wire assembly.

References

[1] Rath & Strong's Six Sigma Leadership Handbook, 1st ed., John Wiley & Sons Inc., Hoboken, New Jersey, 2003
 [2] Handbook of Performability Engineering, 1st ed., RAMS Consultants, Rajasthan, India, 2008