Evaluation of Pre-Oxide Guide Wires to Reduce Teflon Coating Damage

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Abstract *— Abbott Vascular Barceloneta, a guide wire manufacturer, has an overall scrap rate of 14%, of which approximately 50% is due to Teflon coating damage. An engineering study was performed to identify if new material with a pre-oxide layer could be used to manufacture guide wires without cable breakage and if it would produce less Teflon coating damage. The study found that all cables were manufactured without problems and that the experimental lot showed a 10.1% less scrap rate than the control group. This suggests that the oxide layer in the bare guide wire improves the Teflon's adhesion to the wire. Further studies must be made to validate this new material fully. Still, according to the results of this study, this material could make the manufacturing process more efficient and increase output.*

Key Terms *— Adhesion, Manufacturing, Scrap Rate, Surface Finish.*

INTRODUCTION

Abbott Vascular is a company that manufactures medical devices that aid the cardiovascular system. Abbott Vascular at the Barceloneta Site manufactures about 20,000 guide wires daily. This site manufactures almost 30% of all the guide wires used in the United States. Therefore, demand is always high, and production must succeed since these devices are essential for some patients' lives.

Guide wires are manufactured in the tens of thousands daily. However, due to the nature of the manufacturing process, many cables are scrapped because of defects. This scrap rate must be understood and controlled so that manufacturing can reach the daily output of guide wires. Teflon coating damage is the biggest offender by far; approximately 50% of all cables scrapped during manufacturing are due to Teflon coating damage.

This study aims to test a new material with an additional treatment to see if the scrap rate can be reduced. This scrap rate reduction could mean thousands of dollars a year saved.

The main goal of this project is to understand if this new material, when used to manufacture guide wires, will produce a lower scrap rate when compared with the material currently used. The reason behind lowering the scrap rate is that in being more efficient in the guide wire production, the manufacturing cost falls, and output increases. Since this is a new material, it is essential to test if the material can go through the manufacturing process the same way so that it does not affect the final product.

This paper discusses the experimental procedures, hypothesis, and results obtained throughout the study. Also, a literature review on this topic is presented to understand this experiment's basis and the hypothesis. Finally, a discussion of what these results mean and future work that must be done.

LITERATURE REVIEW

This section covers key technical aspects of Teflon coating. These include the purpose of having a guide wire with Teflon coating and the importance of its uniform consistency for the surgeon and the patient’s health, as well as how the Teflon interacts with heat and friction and how the surface preparation of stainless steel improves Teflon adherence.

Teflon Coating in Guide Wires

All guide wires manufactured at Abbott Vascular have a Teflon or polytetrafluoroethylene (PTFE) coating around the wire's core. This coating is performed at the beginning of the process, and for the cable to be acceptable, there must be no damage to the cable. The purpose of this Teflon coating is to decrease the cable's friction when used in arteries, thanks to its hydrophobic properties. Since filaments or peeling from Teflon due to friction can cause serious health problems, surgeons rely on consistent tactile feedback when using coated guidewires to detect obstructions. To ensure this feedback remains reliable, the coating on the guidewires must maintain uniform consistency [1].

Throughout the manufacturing process, the guide wire goes through more than 50 stations, which can cause friction to the cable that already has the Teflon coating adhered. Therefore, considering how these materials react to friction, it turns out that Teflon changes its chemical molecules when exposed to high friction. Therefore, when PTFE was applied to stainless steel and then subjected to friction, filaments of PTFE were found to detach from the stainless steel [2].

Improvement in Teflon adherence to Stainless Steel

During the adhesion of the Teflon to the cable, heat treatment and an accelerator mixture are given to improve adherence. Performance in reducing filaments or peeling has improved by adding different components while preparing the Teflon mix. Combinations of Teflon have demonstrated better performance by reducing the friction coefficient when subjected to high-temperature treatment. High temperatures provide a curing effect on the Teflon mix, improving its surface adhesion [3].

Heat treatment of 800 to 1200 °C on stainless steel produces an oxide coating, creating a rough surface or porosity [4]. Although this oxide layer may cause some issues due to corrosion in some applications, it may be beneficial for guide wire applications. These benefits arise from the need to reduce Teflon peeling by increasing porosity, which improves Teflon adhesion. Adequate surface preparation can be achieved by appropriately applying heat or friction to a surface. In the case of heat treatment of stainless steel, two things are accomplished: the creation of surface porosity and the elimination of contaminants like oil particulates [5].

ANALYSIS APPROACH

This section explains the study's layout, the procedure used during experimentation, and the expected results or hypothesis. In addition, the section goes into the study's objectives and their importance.

Experimental Study for Pre-Oxide Spool vs Standard Spool

To understand the layout and sequence of the experiment, it is essential to have at least a basic understanding of the most critical manufacturing processes used in this experiment. This experiment consists of manufacturing cables throughout fifteen stations. These are the stations that are considered the most critical:

- Reel to Reel: Station where the Teflon is adhered to bare stainless steel cable spool.
- Wire Straightener: Removes the material memory of the cable and straightens the cable.
- Burn-in Oven: It takes the cable for a heat treatment to remove the stress from the cable and make it more malleable.
- Resistance Welding: Welds the stainless-steel part of the cable to a nitinol part, which extends the wire's length.
- DHD Weld Flash Removal: Removes excess metal from welding.
- CAM Grind: Performs a parabolic grind of the Distal (the part that goes inside the patient) to a specific outer diameter.

Two lots containing 600 units were created for the experiment procedure. The experimental lot had the stainless-steel stool with the additional heat treatment that made an oxide layer, and the control lot had a standard stainless-steel spool without the oxide layer. Both lots were processed through the same procedure and inspected at the same inspection points. The operator's inspection processes were modified to benefit the experiment.

Currently, the manufacturing process instructs the operator to check various defects that can affect the quality of the product. However, these were engineering lots, meaning they would not be for human use. Because of this, the inspection process was modified to inspect only defects related to Teflon coating damage, which is the defect this experiment targets.

The hypothesis behind the project is that adding a treatment to the cable before manufacturing will improve the Teflon adhesion to the cable, therefore reducing the Teflon coating damage caused throughout the manufacturing processes by 10% or more. The additional process is simply a heat treatment of the cable, which will cause a layer of oxide to form on the surface of the cable. This oxide will cause the Teflon to adhere better.

Experiment Objectives

There were two main objectives in this experiment. First, to obtain the scrap rate from Teflon Coating Damage defect from both lots and compare them to see if there is a significant difference between them. Depending on the difference between them, it could be concluded that the use of new material with an oxide layer shows no significant difference with less than 10% improvement and is not worth implementing; the experimental lot performs worse and is not worth implementing, or the experimental lot shows a significant improvement of more than 10% and the new material should enter validation stages.

Secondly, to verify that the new material has no adverse effect on manufacturing. It was important that 100% of all cables in both lots could be manufactured in all the stations and that no breakages occurred. Additionally, observation during the welding process was made to ensure no additional difficulties or differences in the success rate.

RESULTS

Figure 1 shows the experimental results regarding the quantity of Teflon coating damage reported in each station with inspection points. There is a significant difference between the control lot and the experimental lot. Table 1 shows the same results in numerical. Considering the results of the two most critical stations, which historically generate the most Teflon coating damage, wire straightener, and CAM grind. It can be observed that the control lot had almost 50% more scrap in both stations. When viewing the overall performance, the experimental lot with the oxide layer had a 10.1% less scrap rate than the control lot. Additionally, no breakages were reported throughout the manufacturing, and the resistance welding process showed no difference in success rate when comparing both lots.

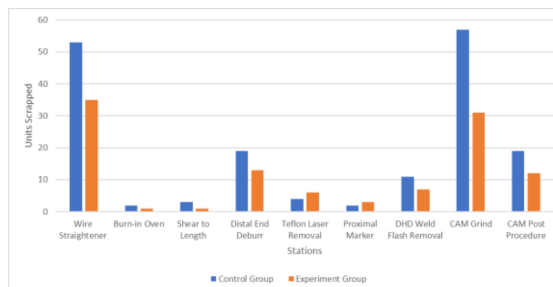

Figure 1
Scrap Quantity: Control Vs. Experiment

Table 1
Stations Scrap Data

Station	Control Lot	Experiment Lot
Wire Straightener	53	35
Burn-in Oven	2	1
Shear to Length	3	1
Distal End Deburr	19	13
Teflon Laser Removal	4	6
Proximal Marker	2	3
DHD Weld Flash Removal	11	7
CAM Grind	57	31
CAM Post Procedure	19	12
Total	170	109
Scrap Rate	28.3%	18.2%

CONCLUSIONS

This experimental study aimed to understand the difference in scrap rate between two lots with the same variables, except for the stainless-steel spool material. Understanding the manufacturing process of this material was a viable option to reduce Teflon coating damage throughout the process.

This experiment has shown how this "pre-oxide" stainless steel is expected to behave during manufacturing. Both objectives were achieved, and a significant difference was observed between both lots. The experimental lot shows a 10.1% less scrap rate than the control lot, which confirms the hypothesis of this experiment. This implies that the additional oxide layer improved the Teflon adhesion to the guide wire, as the literature indicated.

Since the hypothesis was confirmed, this study suggests that this new material can improve Teflon coating damage across all manufacturing processes and improve efficiency and outputs for commercial lots.

As future work, it is expected to complete the material's validation by manufacturing the lots up to the Finished Good level and sending them for testing and confirmation that they are acceptable for human use. Since all Abbott guide wire products are FDA-approved, to see these monetary results, this new pre-oxide material must be validated in much more rigorous studies to confirm these results and prove that no adverse effects on patients can occur if Abbott implements this material.

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