Scrap Reduction of Ventral Hernia Product in Foil Pouches for Manufacturing Line #7

Hector L. Matos Torres
Master in Engineering Management Program
Dr. Hector J. Cruzado
Graduate School
Polytechnic University of Puerto Rico

Abstract — *Scrap generated in finished products is one of the top contributors that negatively impact the production goals and budget in most of the production industries. This paper shows a scrap reduction project conducted in a medical device company. The aim of the project was to reduce the scrap generated in the final seal operation, specially scrap in foil pouches for the ventral hernial repair product. The project was worked by focusing on finding the source of scrap and implementing corrective actions based on the findings. It was found that the cause of the scrap was a combination o of equipment and training opportunities. The procedures were updated, and corrective actions were taken in the sealing equipment. This corrective action leads to achieve the goal of reducing the scrap and increase the production output.*

Key Terms —*Foil, Pouch, Sealing, Yield*

INTRODUCTION

Cost savings projects are one of the strategies that production companies use to reduce costs and increase product value. The project took place in the medical device company Becton and Dickinson, Humacao plant, at the Project Engineering Department. The team is responsible of performing the cost savings projects across existing products in the plant.

As part of the cost savings project identification process, the fiscal year 2020 scrap report was verified to identify the top offenders scrap generators among the products in the plant. In the report it was noticed that the ventral hernia repair mesh product was one of the major sources of $50,000 worth of scrap.

The ventral hernia product is designed to repair the intraabdominal tissue disruption caused by abdominal hernias [1]. The product consist of a polypropylene mesh combined with a coating designed for better adhesion of the device into the muscular tissue. As part of the manufacturing process, when the finish good is completed, the mesh is placed in a foil pouch to keep the integrity of the sterile product. Figure 1 shows the finished product and the foil pouch used to place the mesh.

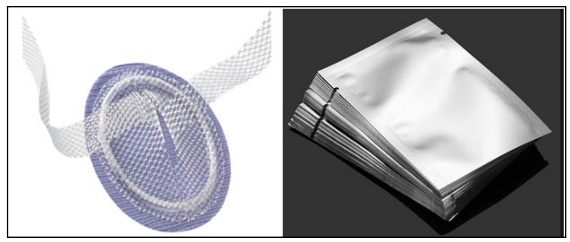

Figure 1
Product and Packaging Illustration

The project was worked using a similar approach of the DMAIC (Define-Measure-Analyze-Improve- Control) methodology which allows study and analysis of the problem, as well as the approach for the possible solutions. The project aimed to identify the sources of scrap, the root cause of scrap, implement corrective actions that reduce the scrap and the verification of the effectives of the implementation measures. The tangibles objectives of the project are the following:

- Reduce the scrap of foil pouches by 80%
- Scrap reduction resulting in $40k in savings
- Increase production output by 10%

ANALYSIS APPROACH

The analysis process was divided in two major steps: collecting data and finding the root cause for the scrap.

Data Collection and Analysis

A total of six weeks of the most recent scrap generated was collected for the analysis. Once the data was collected, a Pareto chart was plotted to visualize the frequency of defects and the cumulative impact. This was used to identify the major offenders as well as to select the defects that will be part of the scope of the project. In Figure 2 it can be observed that Marks and Particulate accounts for 81.5% of the total scrap data for the data collected period, so these two defects turned into the focus of this project.

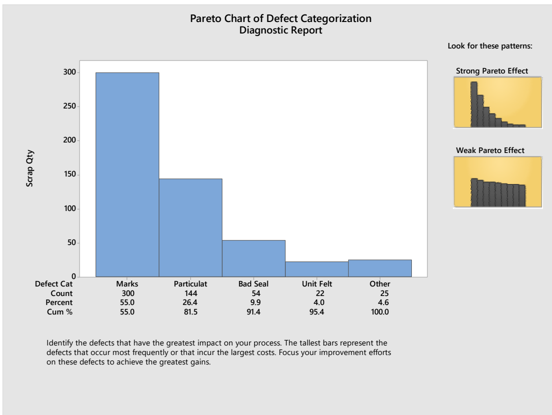

Figure 2
Pareto Chart of Defects

Root cause analysis

A fishbone diagram was used to evaluate the causes of the scrap on the pouches due to particulate and marks. The fishbone is a great systematic tool used for looking at effects and comparing them against the cause that contribute to the defects [2]. As observed Figure 3, there are multiple possible causes for the scrap generated, however, due to the time constraint and resource availability, the following causes were the selected for further analysis:

- Visual Standard
- Manufacturing Procedures
- Preventive Maintenance
- Seal Bar Teflon

The visual standard was revised, and it was noticed that the procedure does not specify about marks on pouches, even when the lot history record sheet provide a space for scrap units for marks. The findings lead to challenge the marks on the pouches and further investigation on marks were performed that lead to changes in the visual standard procedures. Additionally, it was found that the manufacturing procedure is not specific about the process of measuring the size of the particles found in the sterile barrier.

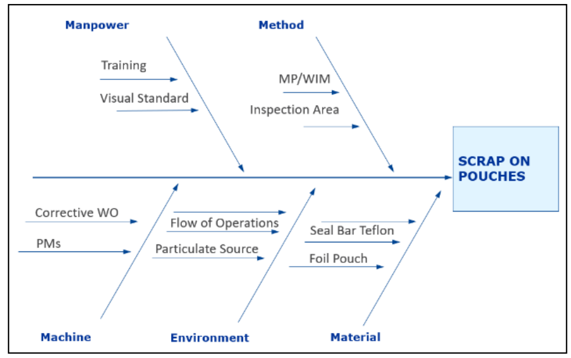

Figure 3
Fishbone diagram

After realizing that the marks on pouches are not a defect established in the procedure, it was decided to test the pouches to verify the effects of the marks in the pouch and to corroborate the seal barrier integrity of the product. Testing the integrity of the seal barrier is an integral part of the sterile product of medical devices as established per the FDA and the American Society for Testing and Materials [3]. The test selected to be conducted was the seal strength test and the dye penetration leak test. The testing procedure and results can be found in the results section of this document.

The next activity of the root cause analysis was the verification of the preventive maintenance record. The sealer machine is cleaned every 2 weeks per in the preventive maintenance. During the data analysis it was observed that the scrap due to particles increase exponential after 1 week of cleaning the sealer. Thus, the preventive maintenance is one of the key contributors of scrap due to particles.

In addition, the thickness of the Teflon sheet was compared to other product lines and it was noticed that the thickness of the sheet was 25% less thick than similar sealer in the plants. The Teflon sheet is used to provide cushion when the seal bar hits the pouch and avoid the transfer of marks to the seal barrier. A brief analysis of the scrap data on those sealer was analyzed, and significant less scrap was observed. Based on that, it was concluded that the Teflon sheet thickness was one of the contributors of the marks on the pouches.

RESULTS

The results that will be discussed in this section are for the pouch seal strength testing and for the pouch leak test.

Seal Strength Pouch Testing Results

After reviewing the data and choosing the defects top offenders to analyze, the scrap pouches that had marks were tested using the pull test method. This consists on pulling the strings of the pouch layers and measuring the resistance force before the separation of the layers. This test is used to measure the strength of the seal and ensuring proper bonding of the sealing barrier [4]. On the same pouch, a non marked area was tested using the same method and both measures were compared using a paired T test. The paired T test is used to compare the means and standard deviation for two groups that are related to determine if there are significant difference between the data groups [5]. In Figure 4, it can be observed in the comments section that there is not enough evidence to conclude that the means differs from the mark area and the non mark area on the pouch with a P value of 0.866 with a 0.05 significance level.

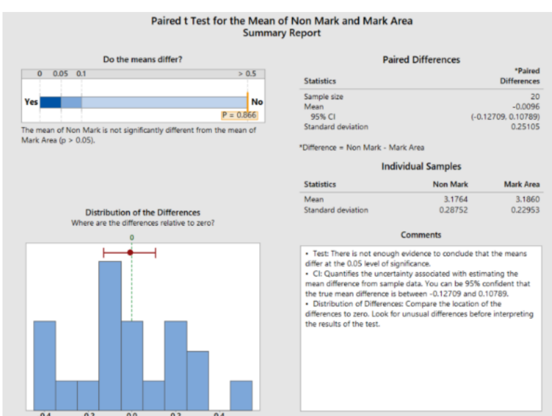

Figure 4

Paired T Test mark area on pouch vs non mark on pouch

Leak Test Results

For the leak test, a dye penetrant solution was applied through the supplier opening of the pouch up to the seal edge to visualize if there are leaks in the seal barrier of pouches. A total of 119 pouches with marks were selected for the testing of pouches as per standard procedures. This was the minimum sampling size requirement. The acceptance criteria for testing are 0 defects for attribute data since a leakage found is the highest severity per the product failure mode document.

The testing was conducted, and no leakage was found in any of the tested pouches. Based on the results obtained, it can be concluded that the marks on the pouches do not have a significant impact in the seal integrity of the pouches and the pouches don't required to be scrapped if they comply with the aesthetics requirements per the procedures.

DISCUSSION

Corrective Actions Implementation

Based on results obtained it was decided that the solutions for the scrap reduction will be divided in four approaches that combined, will provide a robust solution for the problem. The implemented actions are:

- **Visual Standard Procedure Changes:** The visual standard procedure was updated to include specific details regarding acceptable marks on pouches. This procedure change will ensure that there will ne no scrap on acceptable units.
- **Sealing Procedures changes:** The procedure was updated to clarify the instructions regarding the inspection of pouches. The procedure now allows to place the aside and perform an inspection using the chart that measures the particulate dimension and decide to accept or reject units.
- **Sealer Preventive Maintenance Update:** The preventive maintenance frequency for the sealer machine was updated from each 2 weeks to 1

week in order to reduce the particulate residual in the sealing bar.

- **Seal Bar Teflon Sheet Change:** The bar sealers Teflon sheet used for mitigating the impact on the sealer bar was changed for a thicker sheet to reduce the marks on the pouches caused by the impact of the sealing.

Effectiveness Verification and Control

After the implementation of the aforementioned measures, the scrap generated in the manufacturing line was collected for two weeks for the effectiveness verification of the project as part of the control phase. Although two weeks of data is a small sample size, it can be observed in Figure 5 that the scrap generated due to marks and particulate was reduced significantly in comparison with the data obtained during the first collection of data shown in Figure 4.

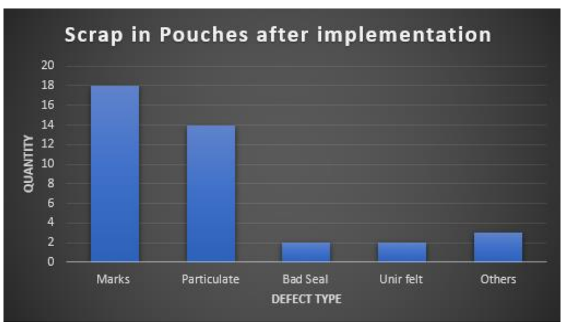

Figure 5
Scrap in Pouches after corrective actions

For instance, during the first period of data collection, a total of 300 units with scrap due to marks were found for six weeks, while after the implementation only 18 units were scrapped due to marks in two weeks and 12 with particulate compared with the 144 found in the first period. Using data from two weeks before implementation, the reduction of scrap is 82% for marks and 75.47% for particulate, as observed in Table 1.

As observed in Figure 5 and Table 1, the scrap was significantly reduced for both marks and particulate defects. Since the defects for marks is the one with more frequency, the principal goal of reducing the scrap by 80% was considered achieved. However, due to the small sampling period, it is recommended to keep tracking the scrap for at least two months in a weekly basis in order to react to any increase of scrap or negative trend in the data.

Table 1
Scrap Reduction Percent Comparison

Defect Type	Before	After	Reduction	Reduction %
Marks	100	18	82	82
Particulate	53	13	40	75.47

Conclusion

It can be stated that the objectives and main purpose of project were achieved. The main sources and causes of scrap on foil pouches were identified and corrections actions were implemented. These corrections actions will ensure the achievement of the goal of reducing scrap by 80%, leading to an estimated annual savings of 40k in materials and labor as expected. Additionally, it will improve the line yield and reduces the rework activities. The implementation of the project provides additional opportunities to extend the project corrective actions to all the manufacturing lines in the plant. Management is looking forward to this since it can provide additional savings for higher cost products.

References

[1] VentrioTM Hernia Patch. (n.d.). BD. Retrieved May 16, 2021, from https://www.bd.com/en-us/offerings/capabilities/hernia-repair-and-fixation/hernia-repair-mesh/synthetic-mesh/ventrio-hernia-patch

[2] Root Cause Analysis. (2021, January 21). Department of Enterprise Services. Available: Root Cause Analysis | Department of Enterprise Services (wa.gov)

[3] Sand, C. K. (2019, July 1). Testing the Integrity of Package Seals - IFT.org. IFT. Available: https://www.ift.org/news-and-publications/food-technology-magazine/issues/2019/july/columns/packaging-seals-tests-standards

[4] Strength and integrity, part two: Basics of seal-strength testing. (2020, June 22). Available: https://www.packagingdigest.com/testing/strength-and-integrity-part-two-basics-seal-strength-testing

[5] Gleichmann, N, Technology Networks. (2020, February 14). Paired vs Unpaired T-Test: Differences, Assumptions and Hypotheses. Informatics from Technology Networks. Available: https://www.technologynetworks.com/informatics/articles/paired-vs-unpaired-t-test-differences-assumptions-and-hypotheses-330826